CHEMSERVICE

REGULATORY MANAGEMENT OPTION ANALYSIS FOR FLUOROPOLYMERS

Final report

prepared for

Fluoropolymers Group (FPG) of PlasticsEurope

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REGULATORY MANAGEMENT OPTION ANALYSIS FOR FLUOROPOLYMERS

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PlasticsEurope
Association of Plastics Manufacturers
Fluoropolymers Product Group

Brussels, September 2021

FOREWORD

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,

Nicolas Robin
Director
Fluoropolymer Products Group

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List of some commonly used abbreviations and acronyms

ACM	Acrylic rubber
ACS	(France) Certificate of Sanitary Compliance
AEM	Ethylene-acrylic rubber
BAT	Best available techniques
CBI	Confidential business information
CHP	Combined Heat and Power plant
CLH	Harmonised classification and labelling
CLP	EU Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic, or toxic to reproduction
COM	European Commission
CSR	Chemical safety report
CT	Computerised tomography
C&L	Classification & Labelling Inventory
D_{ow}	Octanol-water distribution coefficient
DU(s)	Downstream user(s)
ECHA	European Chemicals Agency
EFSA	European Food Safety Agency
EMAS	EU Regulation 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme
EPA	(United States) Environmental Protection Agency
ES	Exposure scenario
eSDS(s)	extended Safety Data Sheet(s)
EU	European Union
FCM(s)	Food contact material(s)
FDA	(United States) Food and Drug Administration
FP(s)	Fluoropolymer(s)
FPG	Fluoropolymer Group of PlasticsEurope
GAC	Granular activated carbon
HEPA	High efficiency particulate air
HNBR	Hydrogenated nitrile rubber
HPLC	High performance liquid chromatography
IE	Ion exchange
IEM(s)	Ion exchange membrane(s)
ISO	International Organization for Standardization

K_{OC}	Organic carbon-water partition coefficient
LED	Light emitting diode
MEA(s)	Membrane electrode assembly(ies)
MEMS(s)	Micro-electro-mechanical system(s)
Mn	Number-average molecular weight
MRI	Magnetic resonance imaging
MSCA(s)	Member State Competent Authority(ies)
MW	Molecular weight
NBR	Nitrile rubber
OC(s)	Operating condition(s)
OML	Overall migration limit
OHSAS	Occupational Health and Safety Assessment Series
PBT(s)	Persistent, bioaccumulative, and toxic
PEM	Proton exchange membrane
PFAS	Per-and polyfluoroalkyl substances
PFAAs	Perfluoroalkyl acids (and its salts)
PFHxA	Perfluorohexanoic acid (and its salts)
PFNA	Perfluorononanoic acid (and it salts)
PFOA	Perfluorooctanoic acid (and its salts)
PFOS	Perfluorooctane sulfonic acid (and it salts)
PFPE(s)	Perfluoropolyether(s)
PLC(s)	Polymer(s) of low concern
POP	Persistent Organic Pollutant
PMT	Persistent, mobile, and toxic
PRR	Polymers requiring registration
PV	Photovoltaic
RAC	Risk Assessment Committee
RC	Responsible care
REACH	EU Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RFG(s)	Reactive functional group(s)
RMO(s)	Regulatory management option(s)
RMOA(s)	Regulatory management option analysis
RMM(s)	Risk management measure(s)
RoI	Registry of intentions
RTO	Regenerative thermal oxidation
R&D	Research and development
SEA	Socio-Economic Analysis

SEAC	Socio-Economic Analysis Committee
SME	Small and medium enterprises
SML(s)	Specific migration limit(s)
SVHC	Substance of very high concern
TWA	Time-weighted average
UBA	German Environment Agency
UPLC	Ultra-performance liquid chromatography
USA	United States of America
US EPA	United States Environmental Protection Agency
UV	Ultraviolet radiation
VII	Voluntary Industry Initiative
VOC(s)	Volatile organic compound(s)
vPvB	Very persistent and very bioaccumulative
vPvM	Very persistent and very mobile
WRAS	(United Kingdom) Water Regulations Advisory Scheme

Executive summary

The Fluoropolymer Group (FPG) of PlasticsEurope requested Chemservice to develop a Regulatory Management Option Analysis (RMOA) for fluoropolymers (FPs). 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. Under the RMOA, all the relevant RMOs are analysed following a fixed system, by evaluating their expected impact against a selection of criteria and factors. The outcome of an RMOA is expected to facilitate the adaptation of industry to future regulatory trends on their materials, and to help the EU regulators to take decisions based on facts and evidence. For this purpose, Chemservice has developed a robust methodology, based on existing guidance documents available from different sources, which has been applied to the case of FPs.

FPs are polymers with fluorine atoms directly attached to their carbon-only backbone (with the exception of perfluoropolyethers). They represent a distinct subset of polymers containing carbon-fluorine bonds, with unique physico-chemical properties that render these specialty materials virtually chemically inert, non-wetting, non-stick, and highly resistant to temperature, fire, and weather. They are currently regarded by industry as being irreplaceable in many applications because their unique combination of specific properties, which are critical to ensure optimal performance in many industrial applications, cannot be guaranteed by other materials. For this reason, they are considered to be materials with high societal value.

Due to their chemical structure, FPs are included in the broad group of Per-and polyfluoroalkyl substances (PFAS). Certain substances within this group, short and long chain per- and polyfluoroalkyl carboxylic acids and -sulfonic acids, have been under regulatory scrutiny over the past years, for instance due to their (presumed) toxic effects on humans, in combination with their potential to bioaccumulate, to be persistent, and/or mobile in the environment. Different regulatory processes have been launched worldwide to address the concerns related to individual substances pertaining to the PFAS group. More recently, Competent Authorities from five Member States within the European Economic Area have initiated a procedure to prepare a joint restriction proposal under the REACH Regulation to limit the risks to human health and the environment from the manufacture and use of all substances considered to be covered under the PFAS family based on structure alone, which could impact more than 4,000 chemicals. While FPs may be deemed to match the traditional definition of PFAS, the industry perspective has always been that they will display different environmental and toxicological properties when compared to other members of the PFAS group, and that, for this reason, they should be considered separately from any regulatory initiative on PFAS. Indeed, the main FPs are considered to meet the criteria to be described as Polymers of Low Concern (PLC) and are characterised by their high stability and the lack of environmental degradability. They are expected to be non-toxic and non-bioaccumulative.

The main concerns related to FPs, as suggested by various parties, are not linked to the polymer as such, but to other chemicals used in or derived from the manufacturing process (e.g., PFAS polymerization aids and residual monomers), as well as to the purities of the FP products that are placed on the market. In addition, by-products that could be generated during end-of-life treatment might also be a reason of concern related to FPs. Indeed, the manufacturing process of FPs involves, in some cases, the use of other substances that belong to the PFAS group as polymerization aids. Some of these substances may generate a risk to human health or the environment if they are released without any emission control. Furthermore, some FPs may contain remaining substances coming from the polymerisation process (e.g., unreacted monomers, oligomers of low molecular weight, minor levels of PFAS polymerization aids, or other by-products generated during the reaction step) which could themselves lead to situations of concern. Finally, the handling of waste coming from FP products, or from articles that have been assembled using FPs could pose environmental risks, as this may involve the generation of by-products such as greenhouse gases if waste is incinerated. While landfilling of waste containing FPs is not considered to be a step of similar concern to incineration, due to the lack of degradability of FPs, it could be an area in which further evaluations are necessary.

These situations of potential concern related to the life-cycle of FPs have generated debate among the scientific community, which has led the Member States involved in the preparation of the PFAS REACH restriction to indicate that FPs could in principle be covered in such a restriction. The objective of this RMOA is therefore to evaluate if this position is justified and proportionate, and to explore if any other RMO is available that would efficiently address the concerns related to FP products, while resulting in limited impact to the different supply chains and economic sectors that heavily rely on the availability of FPs.

In this RMOA, the different FP substances are described, and their properties detailed by referring to the existing scientific information available. The main situations related to potential exposure and risk from the manufacture and use of FPs are presented, as well as an exhaustive description on the uses and applications of FPs, including details on the socio-economic value they bring to society and the reasons why they are irreplaceable for many key applications. It is to be noted that some of those applications are considered to be critical to ensure key objectives of the European Union, in terms of decarbonization, transition to clean energies, and enabling competitiveness and a digital transition of the EU economy. Some uses of FPs are as well related to ensuring health and safety of workers, and ultimately of the general public. Information on potential alternatives, including justification of why, in the vast majority of cases, substitution is not possible is also provided.

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 from 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.

These RMOs are evaluated in more detail according to the conditions laid out in the RMOA methodology that has been followed. A score is assigned to each RMO by comparing the outcome that it is expected to yield against a series of factors. The final scores of the different RMOs are compared, which results in the ranking of RMOs and selection of the most appropriate RMO, or combination of RMOs. Uncertainties related to the evaluation and assignment of scores are also discussed and taken into consideration.

The overall score derived for each RMO is as follows:

- RMO 1: -3.25
- RMO 2: +4.13
- RMO 3: +14.13
- RMO 4: +15.50

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, and the use of polymerization aids to continue with the manufacture of FPs in the EU should be allowed by the regulators. 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. This commitment should follow the typical hierarchy of risk management: substitution (if possible), minimisation of use, and control of the remaining risks. The REACH restriction would need to establish, in parallel, adequate controls to ensure that imported FP products do not result in higher risk for downstream users than those FP products manufactured in the EU. In parallel, EU legislation dealing with industrial emissions and waste should be reviewed and updated, in order to grant that adequate technical controls are put in place to minimise to the furthest possible extent any risk derived from the disposal of FP products and from articles containing FPs.

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. The members of the FPG are committed to work together 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, or even to remove such risks wherever possible, with a strong emphasis on R&D for a continued improvement of the polymerisation process. This will be done with a clear schedule and following transparency principles and agreements to monitor progress. The evaluation and conclusions of this RMOA are based on the certainty that such objectives are feasible and will be achieved.

1. INTRODUCTION

1.1. Scope of the RMOA and data collection

Per-and polyfluoroalkyl substances (PFAS) are a large group of highly fluorinated synthetic substances. Fluoropolymers (FPs), which are high molecular weight polymers with unique properties, could be regarded as a distinct class under the polymer category of PFAS (Henry et al., 2018).

In May 2020, four European Union (EU) Member State Competent Authorities (MSCAs), namely the Netherlands, Germany, Denmark, and Sweden, plus Norway, informed that they had agreed to prepare a joint restriction proposal under the REACH Regulation (Regulation (EC) No 1907/2006) to limit the risks to human health and the environment from the manufacture and use of a wide range of PFAS (European Commission, 2020a). It is acknowledged that PFAS have generated significant concern in recent years in relation to the negative effects on human health and the environment that some substances pertaining to that group exhibit. Indeed, a number of regulatory actions have been undertaken on this group of chemicals globally (Henry et al., 2018). Preliminary indications suggest that FPs could be included in the original scope of the restriction proposal (Chemical Watch, 2020).

While FPs are regarded as being persistent in the environment and acknowledging that this property may warrant further regulatory consideration, persistence alone does not imply that there is a present or future risk to human health or the environment. REACH has regulated persistence so far in the context of PBTs and vPvBs, where Persistent (P) substances must be associated with the Bioaccumulative (B) and Toxic (T) properties (likewise, the very Persistent (vP) property must be associated with very Bioaccumulative (vB)) to justify qualification as a substance of very high concern. Therefore, persistence on its own does not justify the need for specific Risk Management Measures (RMMs).

However, it is acknowledged that during the manufacture, use and end-of-life treatment of FPs, situations may arise that could generate concern in relation to risks for human health or the environment. Such situations are not directly related to FPs as such, but to other substances being involved in the manufacturing process. Examples of these situations would be emissions from the use of PFAS (typically low molecular weight substances used as polymerisation aids during the manufacturing process), remaining monomers, oligomers, or smaller polymers (with up to about 100 monomer units) in the FPs as they are placed on the market, or by-products generated during waste treatment of articles that contain FP, for example via incineration. However, this last process is not well understood and no clear evidence of PFAS emission has been found (Lohmann et al., 2020).

Taking those concerns into consideration, the scope of this Regulatory Management Option Analysis (RMOA) is to evaluate all the possible regulatory actions that could be put forward on FPs, in order to address such concerns. The objective is to analyse the relevant information available on FPs, related to scientific evidence and socio-economic importance, and to conclude on the best possible option that will ensure adequate control of risks, while maintaining a proportionate balance in terms of use of FPs on the EU market. This RMOA will be built using a specific methodology aimed at evaluating information in a systematic and pre-defined way, which is based on a combination of well-known guidance documents on the preparation of RMOAs (See Annex I for further details). A variety of data sources will be used, the most important being the following:

- Documentation developed by the Fluoropolymer Group (FPG)[1] of PlasticsEurope over the past years, including the responses to different calls for evidence and public consultations within the regulatory actions promoted by EU Authorities on some substances of interest for the FPG members.
- Scientific literature related to PFAS and FPs.
- A Socio-Economic Analysis (SEA) on FPs developed at request of the FPG (PlasticsEurope, 2017).
- Responses received at the beginning of 2021 (January and February) to an RMOA questionnaire, developed specifically for this action, that was delivered to manufacturers, importers, and downstream users (DUs) within the European supply chain of FPs in early December 2020 (See Annex II for details on the questionnaire).
- One-to-one calls with all the FPG members (face-to face meetings could not be scheduled due to the current COVID-19 pandemic).
- Internal communications with the FPG secretariat, where relevant.

Regarding the data collected from the responses to the RMOA questionnaires, these have been treated as Confidential Business Information (CBI) in nature. For this reason, after the analysis of the replies received, the information has been summarised and aggregated within this report, in order to protect confidentiality and to avoid the identification of any individual respondent. Annex III includes a summary of the main replies and findings from the questionnaires.

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[1] FPG members (December 2020): 3M – Dyneon GmbH; AGC Chemicals Europe, Ltd.; Arkema; Chemours International Operations SARL.; Daikin Chemical Europe GmbH; WL Gore & Associates GmbH.; and Solvay Specialty Polymers SPA.

1.2. Information on any previous RMOA

No previous RMOA has been developed with the intention to specifically cover FPs.

However, as it has been previously mentioned, five MSCAs are currently preparing an RMOA for PFAS, which may include FPs in its initial scope. The activities related to this RMOA have included a call for evidence, which was open from May until the end of July 2020, aimed at collecting information from relevant stakeholders, which is expected to be used to refine the scope of the proposal and to analyse the effectiveness and socio-economic impact of different restriction options. The estimated date for inclusion of the restriction proposal in the Registry of Intentions (RoI) is July 2021, and the expected date for the submission of the Annex XV dossier (restriction proposal) is the end of the first half of 2022.

On the other hand, there are some specific regulatory actions completed or on-going on PFAS. The following examples are given for illustrative purposes and should not be considered an exhaustive list:

- In 2014, Perfluorooctanoic acid (PFOA), its salts and related substances were proposed for restriction in the EU (inclusion in Annex XVII of REACH), but finally they were listed as persistent organic pollutant (POP), according to Regulation 2019/1021, since 4 July 2020. This legislation implements the commitments of the EU under the Stockholm Convention on POPs and under the Protocol to the 1979 Convention on long range transboundary air pollution on POPs.

- The same situation occurred with Perfluorooctane sulfonic acid (PFOS), its salts and related substances, that were deleted in 2010 from Annex XVII of REACH and are now subject to the EU POP Regulation.

- C9-C14 PFCAs, specifically Perfluorononan-1-oic acid (PFNA - C9-PFCA), Nonadecafluorodecanoic acid (PFDA - C10-PFCA), Henicosafluoroundecanoic acid (PFUnDA - C11-PFCA), Tricosafluorododecanoic acid (PFDoDA - C12-PFCA), Pentacosafluorotridecanoic acid (PFTrDA - C13-PFCA), and Heptacosafluorotetradecanoic acid (PFTDA - C14-PFCA) have been proposed for restriction by the German and Swedish MSCAs in March 2017. The process is currently waiting for the decision of the European Commission (COM) as the opinions of the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) of the European Chemicals Agency (ECHA) have been already adopted.

- In April 2018, Perfluorohexane sulfonic acid (PFHxS), its salts and related compounds were proposed for restriction under REACH by the Norwegian MSCA. RAC and SEAC opinions were published in mid-2020. In the meantime, they were proposed for listing in Annex A to the Stockholm Convention as POPs, without specific exemptions. Both decisions are currently pending of final approval.

- The German MSCA is currently managing a restriction proposal for perfluorohexanoic acid (PFHxA), its salts and related substances, a specific class within the PFAS group. The RoI was issued during December 2018, and the restriction dossier was submitted in December 2019. The public consultation was started in March 2020, and its deadline was September 2020. The opinion by the RAC and the SEAC of ECHA is now under development, and the second 60 days public consultation is expected to be launched in July 2021.
- 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid (HFPO-DA), its salts and its acyl halides are considered as Substances of Very High Concern (SVHC) since 16 July 2019. This decision has been contested in front of the Court of Justice of the EU.
- After a proposal of the Norwegian MSCA, perfluorobutane sulfonic acid (PFBS), its salts and related substances have been classified as SVHCs since 16 January 2020
- ECHA is currently working on a restriction proposal for PFAS specifically focused on their use in fire-fighting foams. This process has been commissioned by the European Commission (COM). The RoI was submitted on 1 October 2020, and it is expected that the Annex XV dossier will be presented in October 2021. In this case, the concern assessed is also persistence.

1.3. Identity of the Substance(s)

When evaluating FPs, it is convenient to differentiate between FP substances, FP products, and finished articles containing FPs. This distinction is important due to the different level of potential concern related to them (Lohman et al., 2020).

- An FP substance as such is a material of known chemical structure, defined in most of the cases by specific CAS and/or EC numbers (e.g., Polytetrafluoroethylene - PTFE).
- An FP product is the actual material manufactured and sold by a chemical manufacturer. It can be available in different final forms (e.g., granulates, powder, etc.).
- A finished article containing FPs is the product sold by the producers of finished articles, which have been produced using FP products via different processes, such as moulding or extrusion (e.g., PTFE tape, waterproof clothing with a PTFE membrane, PTFE-coated cookware, PVDF pipes and tubes, PVDF membranes, etc.).

FPs are a family of polymers with fluorine atoms directly attached to their carbon backbone that are manufactured by (co)polymerisation of olefinic monomers. In order to obtain an FP, it is necessary that at least one of these monomers contains a fluorine bond to one or both of the olefinic carbon atoms, so that the carbon-only polymer backbone with fluorine atoms directly bonded to it can be generated (Henry et al., 2018).

FPs should not be confused with other PFAS families that are currently under severe regulatory scrutiny, such as long-chain perfluoroalkyl acids (PFAAs), which includes PFOA and PFOS, and their precursors (substances that may degrade to form PFAAs). These substances are well-known for their hazard properties to human health and the environment, and they have received increased attention from regulators worldwide over the past years.

FPs can be regarded as a specific family inside the broad group of PFAS, due to their specific chemical behaviour and properties: they are biologically stable and chemically inert in presence of virtually any chemical, negligibly soluble in water, non-bioavailable, non-bioaccumulative and non-toxic, non-wetting, non-stick, and highly resistant to temperature, fire, and weather. FPs are extremely stable specialty plastics and elastomers used in a wide range of applications. Perfluoropolyethers (PFPEs) are a separate subset of polymeric PFAS.

1.3.1. Fluoroplastics

The typical monomers used in the manufacture of fluoroplastics include, but are not limited to, tetrafluoroethylene (TFE), hexafluoropropylene (HFP), vinylidene fluoride (VDF or VF2), chlorotrifluoroethylene (CTFE), vinyl fluoride (VF), trifluoroethylene (TrFE) and perfluoroalkyl vinyl ethers (PAVEs) which include trifluoromethyl trifluorovinyl ether (PMVE), pentafluoroethyl trifluorovinyl ether (PEVE) and heptafluoropropyl trifluorovinyl ether (PPVE). In the case of copolymers, monomers that do not contain fluorine attached to the olefinic carbons may be used. These include, but are not limited to, ethylene, propylene and perfluoroalkyl-substituted ethylenes (PlasticsEurope, 2020a).

Representative fluoroplastics include, but are not limited to, polytetrafluoroethylene (PTFE), the TFE-HFP copolymer (FEP), polyvinylidene fluoride (PVDF), polychlorotrifluoroethylene (PCTFE), polyvinyl fluoride (PVF), the ethylene-TFE copolymer (ETFE), the ethylene-CTFE copolymer (ECTFE), the VDF-HFP copolymer (VDF-co-HFP), the VDF-TFE copolymer (VDF-co-TFE), terpolymer of TFE, perfluoroalkyl trifluorovinyl ether and chlorotrifluoroethylene (CPT), terpolymers of TFE, HFP and VDF (THV), terpolymers of TFE, HFP and ethylene (EFEP), polytrifluoroethylene (PTrFE), and perfluorinated polymers with perfluoroalkoxy side-chains resulting from copolymerization of tetrafluoroethylene with either trifluoromethyl trifluorovinyl ether (MFA) or other perfluoroalkyl trifluorovinyl ethers (PFA).

1.3.2. Fluoroelastomers

The typical monomers used in the manufacture of fluoroelastomers include, but are not limited to, VDF, HFP, TFE, CTFE, PAVEs, and propylene, as well as 1-hydropentafluoropropene (HPFP) and 2,3,3,3-Tetrafluoropropene (HFO-1234yf) (PlasticsEurope, 2020a).

Although fluoroelastomers are based on many of the monomers that are also used for the synthesis of fluoroplastics, they are different due to their unique elastomeric properties, resulting from the cross-linking process, with low sub-ambient glass transition temperatures. Cross-linking, known as curing or vulcanizing, is a hardening process that gives polymers their specific elasticity.

Some fluoroelastomers and fluoroplastics are manufactured using the same monomers in their composition and, due to this fact, they share the same chemical identifiers (e.g., CAS number). The reason is that the substance is defined by the number of monomers, but this fact is not sufficient to define if the material is a fluoroelastomer or a fluoroplastic. The inclusion of the substance in one of these subsets of FPs depends on the relative composition ratio of the monomers.

As an example, THV fluoroplastic and FKM#2 fluoroelastomer are both composed of the same three monomers: TFE, HFP and VF2 (VDF). However, the ratio of these three monomers is different in each material. The ratio of the monomers is critically important for obtaining a plastic or a rubber (elastomer) material, as shown in Figure 1 (Ebnesajjad, 2013).

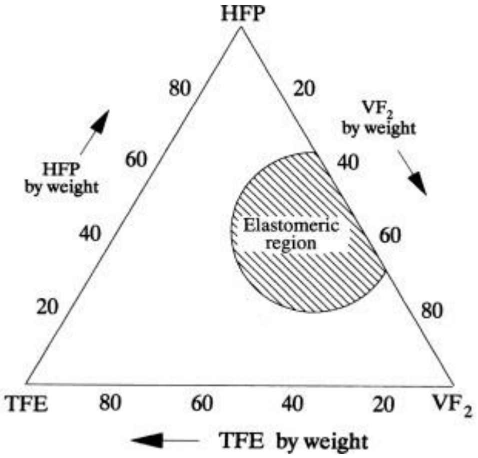

Figure 1. Three-phases diagram of FPs containing TFE, VDF and HFP monomers

1.3.3. Perfluoropolyethers

Perfluoropolyethers (PFPEs) are considered a class of polymeric PFAS. They are different polymers made of perfluoroether monomers, used primarily as lubricants, oils and water repellents (Wang et al., 2020). They differ from the other FPs as they consist of a carbon-oxygen backbone with fluorine atoms directly attached to the carbon atoms.

1.3.4. Examples of FPs

The main source of information related to the identity of FPs that are to be covered in this RMOA has been the responses received to the RMOA questionnaires delivered to manufacturers, importers, and DUs of FPs. This information has been updated and completed with additional data sources, e.g., information from the ECHA website (ECHA, 2021a).

The following tables summarise the information available on the chemical identity of the most common FPs[2]:

Table 1. ECTFE

Name	Ethylene-CTFE copolymer
Other names (trade names and abbreviation)	ECTFE Copolymer of ethylene and chlorotrifluoroethylene
CAS number	25101-45-5
Structure / Formula	$[(CH_2\text{-}CH_2)x\text{-}(CFCl\text{-}CF_2)_y]_n$
ECHA information	No
FP Type	Fluoroplastic

Table 2. ETFE

Name	Ethylene-TFE copolymer
Other names (trade names and abbreviation)	ETFE Ethylene tetrafluoroethylene
CAS number	25038-71-5 / 68258-85-5
Structure / Formula	$[(CF_2\text{-}CF_2)x\text{-}(CH_2\text{-}CH_2)_y]_n$
ECHA information	No
FP Type	Fluoroplastic

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[2] The following tables are a non-exhaustive list of FPs. Other materials not listed here can be considered also inside the FP family.

Table 3. FEP

Name	TFE-HFP copolymer
Regulatory process name	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1,2,2-tetrafluoroethene
Other names (trade names and abbreviation)	FEP Fluorinated ethylene propylene Tetrafluoroethylene-hexafluoropropylene copolymer
EC number	607-524-4
CAS number	25067-11-2
Structure / Formula	$[(CF(CF_3)\text{-}CF_2)_x(CF_2\text{-}CF_2)_y]_n$
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.123.617
FP Type	Fluoroplastic

Table 4. PFA

Name	TFE-Perfluoroalkyl trifluorovinyl ethers copolymer
Other names (trade names and abbreviation)	PFA Perfluoroalkoxy polymer Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethene
CAS number	26655-00-5 / 31784-04-0
Structure / Formula	$(CF_2CF_2)_x[CF_2CF(OCF_2CF_2CF_3)]_y$
ECHA information	No
FP Type	Fluoroplastic

Table 5. PTFE

Name	Polytetrafluoroethylene
Regulatory process name	Ethene, 1,1,2,2-tetrafluoro-, homopolymer
Other names (trade names and abbreviation)	PTFE
EC number	618-337-2
CAS number	9002-84-0
Structure / Formula	$[CF_2\text{-}CF_2]_n$
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.120.367
FP Type	Fluoroplastic

Table 6. PVDF

Name	Polyvinylidene fluoride
Regulatory process name	Ethene, 1,1-difluoro-, homopolymer
Other names (trade names and abbreviation)	PVDF Homopolymer of vinylidene fluoride
EC number	607-458-6
CAS number	24937-79-9
Structure / Formula	$[CH_2\text{-}CF_2]_n$
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.133.181
FP Type	Fluoroplastic

Table 7. P(VDF-TrFE)

Name	VDF TrFE copolymer
Other names (trade names and abbreviation)	Ethene, 1,1,2-trifluoro-, polymer with 1,1-difluoroethene P(VDF-TrFE) Homopolymer of vinylidene fluoride Copolymer of vinylidene fluoride and Trifluoroethylene. Piezotech® FC
CAS number	28960-88-5
Structure / Formula	$[[CH_2\text{-}CF_2]_x[CHF\text{-}CF_2]_y]_n$
ECHA information	No

Table 8. P(VDF-TrFE-CTFE)

Name	VDF-TrFE-CTFE copolymer
Other names (trade names and abbreviation)	Ethene, 1-chloro-1,2,2-trifluoro-, polymer with 1,1-difluoroethene and 1,1,2-trifluoroethene P(VDF-TrFE-CTFE). Copolymers of vinylidene fluoride, trifluoroethylene and chlorotrifluoroethylene, Piezotech® RT F
CAS number	81197-12-8
Structure / Formula	$[[CH_2\text{-}CF_2]_x[CHF\text{-}CF_2]_y[CFCl\text{-}CF_2]_z]_n$
ECHA information	No
FP Type	Fluoroplastic

Table 9. P(VDF-TrFE-CFE)

Name	VDF-TrFE-CFE copolymer
Other names (trade names and abbreviation)	Ethene, 1,1,2-trifluoro-, polymer with 1-chloro-1-fluoroethene and 1,1-difluoroethene P(VDF-TrFE-CFE). Terpolymer of vinylidene fluoride, trifluoroethylene and chlorofluoroethylene, Piezotech® RT F
CAS number	433301-55-4
Structure / Formula	$[[CH_2\text{-}CF_2]_x[CHF\text{-}CF_2]_y[CFCl\text{-}CH_2]_z]_n$
ECHA information	No
FP Type	Fluoroplastic

Table 10. PCTFE

Name	Polymer of chlorotrifluoroethylene
Regulatory process name	Ethene, 1-chloro-1,2,2-trifluoro-, homopolymer
Other names (trade names and abbreviation)	PCTFE Polychlorotrifluoroethylene
EC number	618-336-7
CAS number	9002-83-9
Structure / Formula	$[CF_2\text{-}CFCl]_n$
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.120.473
FP Type	Fluoroplastic

Table 11. EFEP

Name	Copolymer of ethylene, tetrafluoroethylene, and hexafluoropropylene
Other names (trade names and abbreviation)	EFEP Ethylene fluorinated ethylene propylene
CAS number	Confidential
Structure / Formula	$[(CH_2\text{-}CH_2)_x(CF_2\text{-}CF_2)_y(CF(CF_3)\text{-}CF_2)_z]_n$
ECHA information	No
FP Type	Fluoroplastic

Table 12. CPT

Name	Terpolymer of TFE, perfluoroalkyl trifluorovinyl ether and chlorotrifluoroethylene
Other names (trade names and abbreviation)	CPT Copolymer of tetrafluoroethylene and perfluoroalkyl vinyl ether
ECHA information	No
FP Type	Fluoroplastic / Fluoroelastomer

Table 13. VDF-co-HFP / FKM#1

Name	VDF-HFP copolymer
Regulatory process name	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene
IUPAC names	1,1-Difluoretylen-hexafluorpropenpolymer
Other names (trade names and abbreviation)	VDF-co-HFP FKM#1 VDF/HFP VFHP HV PVDF copolymer Copolymer of vinylidene fluoride and hexafluoropropylene Vinylidene fluoride-hexafluoropropylene copolymer Polyvinylidenefluoropropene-hexafluoropropene 1,1-Difluoretylen-hexafluorpropenopolymer
EC number	618-470-6
CAS number	9011-17-0
Structure / Formula	$[CF(CF_3)\text{-}CF_2)_x(CH_2\text{-}CF_2)_y]_n$
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.111.540
FP Type	Fluoroplastic

Table 14. THV / FKM#2

Name	Terpolymer of TFE, HFP and VDF
Regulatory process name	1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and 1,1,2,2-tetrafluoroethene
Other names (trade names and abbreviation)	THV FKM#2 Terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride Vinylidene fluoride-tetrafluoroethylene-hexafluoropropylene copolymer
EC number	607-638-4
CAS number	25190-89-0
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.107.309
FP Type	Fluoroplastic / Fluoroelastomer

Table 15. VTP / FKM#3

Name	Polymer of Vinylidene fluoride, Tetrafluoroethene and Perfluoromethylvinylether
Other names (trade names and abbreviation)	VTP FKM#3 TFE/PMVE/VDF Vinylidene fluoride-tetrafluoroethylene-trifluoro(trifluoromethoxy)ethene copolymer Ethene, tetrafluoro-, polymer with 1,1-difluoroethene and trifluoro(trifluoromethoxy)ethene
CAS number	56357-87-0
Structure / Formula	C7H2F12O
ECHA information	No
FP Type	Fluoroplastic / Fluoroelastomer

Table 16. FFKM

Name	Copolymer of tetrafluoroethylene and perfluoromethylvinylether
Other names (trade names and abbreviation)	FFKM Ethene, tetrafluoro-, polymer with trifluoro(trifluoromethoxy)ethene
CAS number	26425-79-6
Structure / Formula	$[CF(OCF_3)CF_2.CF_2CF_2]_x$
ECHA information	No
FP Type	Fluoroelastomer

Table 17. FEPM

Regulatory process name	1-Propene, polymer with 1,1,2,2-tetrafluoroethene
Other names (trade names and abbreviation)	FEPM TFE/P Propylene tetrafluoroethylene copolymer 1-Propene polymer with tetrafluoroethene Tetrafluoroethylene-propylene copolymer
EC number	608-038-5
CAS number	27029-05-6
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.108.688
FP Type	Fluoroplastic / Fluoroelastomer

Table 18. VDF/HFO-1234yf

Name	1-Propene, 2,3,3,3-tetrafluoro-, polymer with 1,1-difluoroethene
Other names (trade names and abbreviation)	VDF/HFO-1234yf
CAS number	1034381-22-0
ECHA information	No
FP Type	Fluoroplastic / Fluoroelastomer

Table 19. TFE/E/HFP/PMVE/VDF

Name	Polymer of Vinylidene fluoride, Hexafluoropropene, Tetrafluoroethene
Other names (trade names and abbreviation)	TFE/E/HFP/PMVE/VDF 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene, ethene, 1,1,2,2-tetrafluoroethene and 1,1,2-trifluoro-2-(trifluoromethoxy)ethene
CAS number	149935-01-3
Structure / Formula	$(C_3F_6O.C_3F_6.C_2H_4.C_2H_2F_2.C_2F_4)_x$
ECHA information	No
FP Type	Fluoroelastomer

Table 20. TDM

Regulatory process name	Vinylidene fluoride-tetrafluoroethylene-trifluoro(trifluoromethoxy)ethane
Other names (trade names and abbreviation)	TDM Low T FKM Ethene, [difluoro (trifluoromethoxy) methoxy] trifluoro copolymer Ethene, [difluoro(trifluoromethoxy)methoxy]trifluoro-, Polymer with 1,1-difluoroethene
CAS number	870707-45-2
ECHA information	No
FP Type	Fluoroplastic / Fluoroelastomer

Table 21. PFPE 1

Regulatory process name	Poly[oxy[trifluoro(trifluoromethyl)-1,2-ethanediyl]], α-(1,1,2,2,2-pentafluoroethyl)-ω-[tetrafluoro(trifluoromethyl)ethoxy]
IUPAC names	Perfluoroalkylether
Other names (trade names and abbreviation)	PFPE 1 Perfluoropolyether/ Perfluorinated Polyetheroil, for lubricants
EC number	611-940-1
CAS number	60164-51-4
Structure / Formula	$(C_3F_6O)_x.C_5F_{12}O$
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.133.525
FP Type	Perfluoropolyether

Table 22. PFPE 2

Name	Oxetane, 2,2,3,3-tetrafluoro-, homopolymer, fluorinated
Other names (trade names and abbreviation)	PFPE 2
CAS number	113114-19-5
Structure / Formula	$(C_3F_6O)_x.C_5F_{12}O$
ECHA information	No
FP Type	Perfluoropolyether

Table 23. PFPE 3

Regulatory process name	Ethene, 1,1,2,2-tetrafluoro-, oxidized, polymd.
Other names (trade names and abbreviation)	PFPE 3 Ethene, tetrafluoro-, oxidized, polymd. 1,1,2,2-Tetrafluoro-Ethene-, oxidized, polymd.
EC number	615-043-6
CAS number	69991-61-3
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.128.265
FP Type	Perfluoropolyether

Table 24. CAS 185701-88-6

Name	Propanoyl fluoride, 2,3,3,3-tetrafluoro-2-(1,1,2,3,3,3-hexafluoro-2-(heptafluoropropoxy)propoxy)-, polymer with trifluoro(trifluoromethyl)oxirane, reaction products with 3-(ethenyldimethylsilyl)-N-methylbenzenamine
CAS number	185701-88-6
ECHA information	No
FP Type	Fluoroplastic / Fluoroelastomer

Table 25. PFPE 4

Name	1-Propene, 1,1,2,3,3,3-hexafluoro-, oxidized, polymd., reduced, hydrolysed reaction products with ammonia
Other names (trade names and abbreviation)	PFPE 4
CAS number	370097-12-4
ECHA information	No
FP Type	Perfluoropolyether

Table 26. PFPE 5

Regulatory process name	1-Propene, 1,1,2,3,3,3-hexafluoro-, oxidized, polymd.
IUPAC names	1-Propene, 1,1,2,3,3,3-hexafluoro-, oxidized, polymd.
Other names (trade names and abbreviation)	PFPE 5
EC number	615-044-1
CAS number	69991-67-9
Structure / Formula	$CF_3O[-CF(CF_3)CF_2O-]_x(-CF_2O-)_yCF_3$
ECHA information	https://echa.europa.eu/substance-information/-/substanceinfo/100.132.538
FP Type	Perfluoropolyether

Table 27. FEVE

Name	Copolymer of fluoroethylene and vinyl ether
Other names (trade names and abbreviation)	FEVE Fluoro ethylene and vinyl ether
CAS number	146915-43-7 / 207691-69-8
ECHA information	No
FP Type	Fluoroplastic / Fluoroelastomer

Table 28. Fluoropolymer ionomer

Name	Fluoropolymer ionomer
Other names (trade names and abbreviation)	Perfluorinated ionomer Ion conducting fluoropolymer
ECHA information	No
FP Type	Fluoroplastic

Table 29. Amorphous fluoropolymer

Name	Amorphous fluoropolymer
CAS number	101182-89-2
ECHA information	No
FP Type	Fluoroplastic

Table 30.Mixture

Name	Mixture of Ethylene-tetrafluoroethylene copolymer and Vinylidene fluoride-tetrafluoroethylene-hexafluoropropylene copolymer
CAS number	94228-79-2 and 25190-89-0
ECHA information	No
FP Type	Mixture of fluoroplastic and fluoroelastomer

Table 31.VT

Name	VT polymer
ECHA information	No
FP Type	Fluoroplastic

Table 32.PFPE 6

Name	PFPE 6 Poly［oxy(1,1,2,2,3,3-hexafluoro-1,3-propanediyl)］, a-(2-carboxy-1,1,2,2-tetrafluoroethyl)-w-(heptafluoropropoxy)-
CAS number	120895-92-3
ECHA information	No
FP Type	Perfluoropolyether

Table 33.PFPE 7

Regulatory process name	Poly(oxy(trifluoro(trifluoromethyl)-1,2-ethanediyl)), alpha-(1-carboxy-1,2,2,2-tetrafluoroethyl)-omega-(tetrafluoro(trifluoromethyl)ethoxy)-
IUPAC name	Perfluoropolyether carboxylic acid
Name	PFPE 7 Poly(oxy(trifluoro(trifluoromethyl)-1,2-ethanediyl)), alpha-(1-carboxy-1,2,2,2-tetrafluoroethyl)-omega-(tetrafluoro(trifluoromethyl)ethoxy)-
EC number	680-272-0
CAS number	51798-33-5
ECHA information	https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.205.223
FP Type	Perfluoropolyether

Table 34.VdF/TFE

Name	VdF/TFE co-polymer
Other names (trade names and abbreviation)	Copolymer of vinylidene fluoride and tetrafluoroethylene
Structure / Formula	[(CH2-CF2)x(CF2-CF2)y]n
ECHA information	No
FP Type	Fluoroplastic

1.3.5. Manufacturing process

FPs are typically synthesized via free radical polymerization methods (Henry et al., 2018), which consist of a multistep process that includes the reaction of the monomers (that are supplied in liquid and/or gaseous phase) in aqueous medium, halogenated solvents or mixtures of both (Ebnesajjad, 2016). The components are mixed, and the reaction mass is then further processed to achieve the final FP product, which can be obtained in different forms (granulates, fine powders, micropowders, or aqueous dispersions) for packaging and shipping. The manufacture of fluoroelastomers adds an extra step in the manufacturing process. These FPs are manufactured as dispersions, isolated as uncured elastomers, compounded, moulded, and then cross-linked (curing or vulcanizing step) to impart their elasticity.

There are basically two main different methods to perform the polymerization process: emulsion and suspension, although polymerisation in solvent is also used (Ebnesajjad, 2016). The main difference is that emulsion requires the use of polymerization aids, in order to favour the intimate mixing of the monomers to complete an efficient and safe reaction. These aids are typically fluorinated surfactants belonging to the PFAS group of substances, although some manufacturers have developed a process using non fluorinated surfactants (however this process cannot be applied to all types of FPs). FP products manufactured by suspension do not require the use of polymerization aids in their manufacture. Polymerisation in non-aqueous media generally requires the use of per- or polyfluorinated solvents. It is known that the solvents containing hydrogen, chlorine, or bromine atom will lead to chain termination thereby affecting quality of fluoropolymer. The saturated perfluorinated media are therefore used as they do not cause such interference.

In general, suspension polymerization leads to coarse forms of FP products (granulates) while emulsion polymerization results in fine particle size distribution forms (powder) and dispersions. Some FP products are made available in the form of emulsions with submicron FP particle sizes. As example, PTFE is available in granular form (manufactured via suspension polymerization with no polymerization aids), and fine powder and water-based dispersion forms (prepared via emulsion polymerization, using polymerization aids). Each one of these forms are related to the subsequent use of this material: granulates are mainly used for moulding (compression and isostatic) and ram extrusion, powders are used for paste extrusion (as manufacture of the Expanded Polytetrafluoroethylene – ePTFE) or as additive to increase wear resistance or frictional properties of other materials; finally, dispersions are used for coatings and film casting (Teng, 2012).

The main function of the polymerization aids used in the emulsion polymerization is the assurance of the technical properties of the FP products and the improvement of the manufacturing step. This is particularly relevant in cases in which, due to the nature of the applications in which they are intended, ultra-pure FP products are required. It is worth noting that the polymerization aids are used at a very low concentration level, i.e., a few tenths of a percentual value relative to the amount of polymer manufactured (Buck et al., 2011).

According to the literature (Dams et al., 2016), ammonium salts of PFOA and PFOS have been historically the most common PFAS-based polymerization aids used in FP manufacturing. With the findings related to the environmental and health concerns associated with long chain PFAAs, the manufacturers of FP products initiated the development of containment and replacement strategies. The challenge was to ensure that FP products could still be safely manufactured while minimizing the use and emissions derived from polymerization aids.

The strategies of containment involve the recovering, removing, purifying, and recycling of the polymerization aids from off-gases, waste-water streams, aqueous dispersions, and final FP products. The recovery/recycling techniques of the polymerization aids depend on the final form of the FP product: they can be removed when the aqueous emulsion is dried for sale as a solid (in the case of powder), or they can be thermally destroyed at high temperatures during the curing process (in the case of aqueous dispersion).

The recovery/recycling techniques have been applied since the beginning of the 1990s and at the present time, they are installed in many FPs manufacturing facilities around the world and used for a variety of polymerization aids. Recapture rate for fluorinated surfactants of approximately 98% (Dams et al., 2016) is achieved by some companies.

The strategies for replacement are based on the development of alternative polymerization aids with an improved hazard profile, which still meet the technical requirements of the polymerization process. Implementation of different polymerization techniques in which less or no fluorinated surfactants can be used is also relevant. These strategies have been pushed by some regulatory initiatives worldwide, such as the PFOA Stewardship Program of the United States Environmental Protection Agency (US EPA, 2006), which called for the elimination of emissions of PFOA during manufacture and the elimination of PFOA and related substances in FP products by 2015 in the USA, or the restriction of PFOA and its related salts in the EU (ECHA, 2017).

One of the respondents to the RMOA questionnaire stated that they have developed emulsion polymerization processes that do not require the use of PFAS as polymerization aids, and that they expect to reach 100% manufacture of FPs without any PFAS polymerization aid in the coming years. However, it is to be noted that at present, this is not possible for all types of FPs. Research into non-fluorinated polymerisation aids is a lengthy process which may take years; FPs manufactured using alternative polymerisation technologies must be tested along the whole value chain and pass all of the industry standards. Even then, these FPs may not be suitable for all of the potential applications.

Furthermore, other respondents have expressed commitments to reduce emissions from the manufacturing process of FPs of all fluorinated organic compounds, including polymerization aids, raw materials, impurities, and by-products, to air and water.

1.4. Similar Substances/Grouping possibilities

The application of the grouping principle was introduced in REACH in relation to the read-across concept. Read-across is based on the use of data available from one substance to establish conclusions for another structurally similar substance, in terms of physicochemical, toxicological, ecotoxicological and/or environmental fate properties (ECHA, 2013a). The SVHC roadmap to 2020 (ECHA, 2013b) introduces the grouping concept for similar uses. This (technical) functional grouping approach can be understood as a tool to ensure that chemicals with similar hazard properties and same use pattern, resulting from their technical function, are regulated together in the same timeframe in order to avoid regrettable substitution by implementing potential risk management measures jointly on those substances as a group.

Regrettable substitution leads to a non-level playing field in the European chemicals market. When a substance is replaced by another chemical which ultimately leads to equal or higher levels of hazard or risk, the Regulation is introducing a discriminatory factor on the manufacturers and importers of the replaced substance, because this leads to a loss of market share in favour of a substitute substance that does not show any advantage in terms of protection to human health or the environment. This in addition undermines the credibility of the regulatory process.

Within the concept of Sustainable Chemistry (Blum et al., 2017) it is highlighted that in many cases, the function of a chemical is linked to a hazardous property. Therefore substitution requires a robust analysis of whether alternatives are available which fulfil the required function without exhibiting the hazardous property of concern, or similar ones.

In relation to PFAS, their definition is based on structural considerations, rather than on their physicochemical or biological properties: PFAS are taken to be organic fluorine compounds that contain at least one perfluoroalkyl ($C_nF_{2n+1}–$) group, with $n \geq 1$ (Buck et al., 2011). This definition was later broadened to also include perfluoroalkylene groups ($–C_nF_{2n}–$, $n \geq 3$) and perfluoroalkylene ether groups ($–C_nF_{2n}OC_mF_{2m}–$, with both n and $m \geq 1$) (OECD, 2018). In a further expansion of the structural definition, the scope of the Call for Evidence launched by five EEA Member States to assess PFAS in scope of a potential REACH restriction included substances that contain at least one aliphatic $-CF_2-$ or $-CF_3$ element (ECHA, 2020).

This observation explains why the definition of PFAS is based on the mere presence of perfluoroalkyl groups in their structure: all PFAS thus defined are tacitly deemed to be hypothetically capable of transformation to PFAAs, whether or not there are experimental observations or a weight-of-evidence assessment with expert judgment to support this conclusion. However, it is known that certain structures that fall in the PFAS definition such as FPs do not degrade in the environment or in the presence of biota, so they cannot lead to PFAAs of concern (Henry et al., 2018). Still, initiatives suggesting that all the members of the structure-based family of PFAS (including FPs) should be regulated as a group, under the assumption that they all may lead to environmental and/or toxicological concerns equivalent to PFOS, PFOA and the other members of the PFAAs family regulated so far demonstrates a shortcoming of the structure-based classification[3]. Indeed, segmentation according to known properties is essential before assessing sub-groups of the PFAS family, some of which, especially FPs, are considered of low concern. Indiscriminate generalization to the whole family, with vastly diverse properties, would not be grounded on sound science.

FPs are considered a specific group of high molecular weight polymers inside the PFAS family, due to their common and unique physicochemical properties that are distinctly different among the other PFAS. Mainly, FPs do not display the environmental and toxicological properties associated with certain substances in the PFAS family (e.g., water solubility and bioaccumulation). The stability of FPs gives them unique, durable, lasting performance in critical uses and applications. A substantial body of scientific data (Henry et al., 2018) demonstrates that FPs do not pose a significant risk to human health or the environment, because of their unique characteristics. FPs have negligible solubility in water, cannot enter or accumulate in the human bloodstream, and cannot degrade into other PFAS under normal conditions of use. Therefore, it is considered that FP substances do not pose a significant risk to water quality, human health, or the environment.

Moreover, at least four FPs (PTFE, ETFE, FEP, and PFA) have been demonstrated to meet the OECD's criteria for Polymers of Low Concern (PLCs), representing approximately 70% to 75% of the world FPs consumption in 2015 (Henry et al., 2018). Per definition PLCs are polymers deemed to have insignificant environmental and human health impacts. Therefore, these polymers should face reduced regulatory requirements (OECD, 2009). Currently, it is considered that PVDF and VDF-co-HFP can also be regarded as PLC, according to the information submitted by the manufacturers in the responses to the RMOA questionnaire and the position paper prepared by the FPG in response to the call for evidence on the PFAS restriction proposal (PlasticsEurope, 2020b)[4].

For these reasons, efforts by the FP industry strongly advocate for the segmentation of the PFAS family of substances before performing any grouping-based assessment, with the aim to place environmentally stable compounds such as FPs in a separate category.

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[3] Both PFOS and PFOA, as well as their salts and 'related compounds' (sometimes referred to loosely as 'C8 chemistry'), are now regulated globally as 'Persistent Organic Pollutants (POPs)' under the Stockholm Convention and PFOA has been categorized as 'Substances of Very High Concern' under REACH, as have certain homologues of PFOS and PFOA, also belonging to the family of PFAAs, which have so far been the main focus of regulatory attention. Undesirable properties assessed in this respect include persistence, bioaccumulation, hydrogeological mobility, long-range transport, toxicity, and combinations thereof.

[4] At the time of preparation of this RMOA, the FPG is developing arguments to expand the number of FPs that can be considered to meet the PLC criteria.

1.5. Status of the substance(s) under REACH

According to point 9 of Article 2 of the REACH Regulation, the provisions of Titles II (registration of substances) and VI (evaluation) are not applicable to polymers. For this reason, FPs do not appear in the ECHA dissemination website of registered substances (ECHA, 2021a). However, it is possible to find some information on FPs (13 substances from those described in Section 1.3) related to pre-registration. It is worth noting that ECHA has included 3 FPs (PTFE, PVDF, and PCTFE) in the inventory of substances likely to meet the criteria of Annex III to the REACH Regulation. However, as this provision is related with the registration process, it does not have any practical implication for these substances. On the other hand, polymers are not exempted from the provisions of other Titles of the REACH Regulation, such as Title VII on authorization and Title VIII regarding the restriction of dangerous substances.

At this moment, the only regulatory action related to REACH that could directly impact FPs is the RMOA that the MSCAs of the Netherlands, Germany, Denmark, Sweden, and Norway are preparing for PFAS, which is focused on the restriction.

1.6. Description on legal requirements under other EU legislation

While there is an extensive list of chemical regulations affecting PFAS at European level (for example, Drinking Water Directive, Groundwater Directive, Water Framework Directive, Food Contact Regulation, Industrial Emissions Directive, Waste Framework Directive, POPs Regulation, etc.), no specific legislative provisions directly related to the FPs family are available. All the existing regulations are focused on the PFAAs subset and, more specifically, on PFOA and PFOS.

However, as FPs are used to produce non-stick cookware surfaces, as well as medical devices, the analysis of other EU legislation will be focused on these product-specific regulations.

1.6.1. Food contact legislation

The European Food Safety Agency (EFSA) provides recommendations to COM within the EU for the regulation of food contact materials (FCMs), requirements for their evaluation, and authorization of acceptable uses, according to Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (Framework Regulation). FPs clearance is based in part upon the fact that polymers will not migrate into food due to their high molecular weight (Henry et al., 2018).

The EU focuses on potential low molecular weight moieties, such as residual monomers and leachable by-products, rather than on the polymer itself. This is due to the fact that, if the FP-coated food contact articles (e.g., metal cookware) are not properly pre-treated, they could lead to the leaching of non-polymeric PFAS residuals into food during the use phase. It has been hypothesised that these residual PFAS could be the polymerization aids used in the manufacturing process, and/or monomers, oligomers, and other synthesis by-products released due to an incomplete polymerization process (Lohman et al., 2020).

The EU food contact regulation requires that monomers, other raw materials, and additives used to manufacture food contact polymers should be risk assessed and authorized, as described in Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and should adhere to the good manufacturing practice Regulation (2023/2006). This regulation lists authorized substances that are permitted to become in contact with food and it also sets their specific migration limit (SML), which is the maximum permitted amount of substance in food that has been determined not to pose a risk to human health, specifically for individual chemicals (e.g., monomer). The monomers, other starting substances, and additives used to manufacture FPs (e.g., PTFE, FEP, and PFA) have been authorized for food contact uses.

Representative SMLs for the monomers that are relevant for FPs that are currently considered PLCs are given in the following table (Regulation 10/2011):

Table 35. EU SMLs for monomers in representative PLC FPs (in mg monomer/kg food)

PTFE	**FEP**	**ETFE**	**PFA**	**PVDF**	**VDF-co-HFP**
0.05 mg/kg for TFE	0.05 mg/kg for TFE 0.01 mg/kg for HFP	0.05 mg/kg for TFE None for Ethylene	0.05 mg/kg for PMVE 0.05 mg/kg for PPVE None for PEVE	5 mg/kg for VDF	5 mg/kg for VDF 0.01 mg/kg for HFP

The content of PFAS impurities in food-contact articles coated with FPs are managed by manufacturers through the technical specification of the polymer. As stated, there are no specific EU SMLs set for FPs, but they are covered by an overall migration limit (OML) of 10 mg/dm^2, of total constituents released per dm^2 of food contact surface, and 60 mg/kg, of total constituents released per kg of food simulant, in the case of plastic materials and articles that could be brought into contact with food intended for infants and young children (LGC Standards, 2019).

1.6.2. Medical devices legislation

Historically, FPs have been developed for industrial applications but, due to their excellent properties, they have also been used over a number of years in a wide range of medical applications. Regulation 2017/745 should be followed by the manufacturers and marketers of medical devices in the EU, as well as any other applicable national regulation, in order to properly evaluate such devices.

A variety of devices containing FPs have been evaluated over the years, for example (Gardiner, 2015):

- Medical clothing, gowns, sheets, and curtains are made from or coated with PTFE to impart oil, water, and stain resistance.
- FP ionomer is used to dry or humidify breath for anaesthesia and respiratory care as well as for biomedical inserts.
- ePTFE is used as surgical sutures, arterial and stent grafts as well as preformed subcutaneous implants in reconstructive and cosmetic facial surgery.
- The optical properties of FPs have also been explored as components of contact lenses and corneal inlays.

Other examples are the use of PVDF electrospun fibre media technology is enabling the production of high efficiency face masks (i.e., N95, FFP1, FFP2, FFP3, KN95), or the use of PVDF in ultrafiltration membrane for pharmaceutical applications provide high flow rates and throughput, low extractables and broad chemical compatibility.

However, there is no general regulatory approval of an FP for medical uses as individual component of the medical devices. Each specific type of medical device containing FPs must be submitted to appropriate regulatory authorities for approval. Manufacturers of medical devices should carefully determine whether the FP is suitable for the intended use (PlasticsEurope, 2012).

1.7. Regulatory activities outside the EU

Similarly to the EU, there is an extensive list of chemical regulations affecting PFAS worldwide (mainly focused on the long-chain PFAAs subset), but there are not specific legislative provisions directly related to the FPs family specifically. This compliance analysis will be focused, as in the case of the EU Regulations, on food contact and medical devices, specifically in the United States of America (USA).

1.7.1. USA Regulations

In the USA, the Food and Drug Administration (FDA) is responsible for regulation of materials that come in contact with food (considered “indirect food additives”) and food storage or food packaging materials. Submissions to the FDA to support new food contact substances require extensive data submissions, including, for example, the nature and amount of nonvolatile extractives.

FPs are not new substances in applications where they come in contact with food and have longstanding acceptance by US regulators. The FDA has cleared many FPs for use in contact with food (Henry et al., 2018) and, in addition, stabilizers, antioxidants, colorants, and other adjuvants that are not an essential part of the polymerization process have also been cleared by the FDA:

- Polymers in general are considered indirect food additives according to 21CFR, Sect. 174–178.
- FPs (as PTFE, FEP, PFA, and PVDF) are perfluorocarbon resins acceptable for use by application and material type (21 CFR, Sect. 177.1380, 177.1550, and 177.2510 as listed in Appendix A), provided they meet the extractable limits specified in the regulation.
- Other FPs have been the subject of various Food Contact Notification (FCNs)[5]. These FCN listings, unlike Food Additive Regulations, are only applicable to the notifiers who obtained them and their customers.
- Most FDA regulations for antioxidants, stabilizers, and other adjuvants appear in 21 CFR, Sect. 178.

However, manufacturers wishing to use FPs in food contact applications in the US must make their own decision concerning the suitability of the individual FP for the specific intended use (Plastics Industry Association, 2018).

Formal biocompatibility evaluations are required by the FDA to support submissions for approval of medical devices, as small and bigger PTFE tubes, and different small articles and films, used mainly for short term applications.

The International Organization for Standardization (ISO) 10993 Biocompatibility of Medical Devices standards describes a broad array of biocompatibility tests that require consideration for each new device or significant changes to existing devices. The ISO 10993 standards provide guidance for evaluation of the biological response to a medical device. The FDA recognizes and

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[5] Specific FCNs for FPs can be found in https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications (search by CAS number)

uses ISO 10993 standards to guide safety evaluations of medical devices submitted for their approval.

Over the years, medical devices containing FPs (e.g., PTFE, ePTFE and PVDF) have been evaluated using ISO 10993 and have been determined to be biocompatible in their intended uses (Helmus et al., 2008; Henry et al., 2018). However, FDA does not approve individual components of medical devices, such as FPs. The manufacturers and marketers of finished medical devices are responsible for obtaining any required clearance or approval for their devices (Plastics Industry Association, 2018).

2. AVAILABLE INFORMATION ON THE SUBSTANCE(S)

2.1. Hazard information and classification

2.1.1. PBT assessment

The most valuable properties of FPs, which render them unique materials, are their high stability (thermal, chemical, and biological), inertness, and durability, which make them necessary for many diverse and critical industrial applications of high societal value, for which there are no viable alternatives (e.g., medical devices, renewable energy, and automotive and semiconductor applications, among others). However, their persistence, as a consequence of these properties, is the primary concern of regulators regarding the specific FPs family, inside the broad group of PFAS.

Persistent substances are those that fulfil the P-criteria according to Section 1.1.1 of Annex XIII of the REACH Regulation:

- the degradation half-life in marine water is higher than 60 days;
- the degradation half-life in fresh or estuarine water is higher than 40 days;
- the degradation half-life in marine sediment is higher than 180 days;
- the degradation half-life in fresh or estuarine water sediment is higher than 120 days;
- the degradation half-life in soil is higher than 120 days.

It is worth noting that persistence, by definition, is mainly related to the environmental context, although some MSCAs consider that persistent substances may also be harmful to human health. However, although persistence in the environment may justify regulatory attention on a substance, it does not in itself represent a hazard. The REACH Regulation establishes that a substance may be considered as a substance of concern when it is categorized as PBT (or vPvB). In this legal context, hazard can only be justified if persistence is associated with bioaccumulation and toxicity. There is no indication in the REACH Regulation that persistence alone justifies risk management measures because persistence alone, as legally defined, does not imply that there is a present or future risk to human health or the environment.

FPs are persistent substances due to the carbon–fluorine (C–F) bond in their chemical structure. This is the strongest bond between C and any another atom, instilling substances that contain a majority of C–F bonds with stability, inertness, and persistence (Henry et al., 2018). This means that substances containing this chemical bond resist degradation by acids, bases, oxidants, reductants, photolytic processes, microbes, and metabolic processes and, for this reason, they are thermally, chemically, and biologically highly inert. These properties are present when these substances are used, but also in the environment. Therefore, when emitted into the environment (which can occur during all life-cycle stages), they are not able to degrade under environmental conditions. In conclusion, although FPs may meet the REACH definition to be considered persistent, existing information demonstrates that they are not bioavailable, toxic, or even mobile in the environment, and therefore do not meet the PBT criteria.

Henry et al. (2018) argue that FPs are not PBT substances, by taking PTFE (the largest volume substance in the FPs family) as example and considering the proposal for the identification of substances as Persistent, Mobile, and Toxic (PMT) and very Persistent, very Mobile (vPvM) developed by the German Environment Agency (UBA, 2017[6]). The criteria established in this proposal are the following:

- P and vP criteria are the same as Annex XIII of the REACH Regulation.
- M and vM criteria, that are not explicitly defined in the REACH Regulation, are based on the water solubility (≥ 0.15 mg/L), the soil/sediment organic carbon-water partition coefficient (K_{oc}), and the pH dependant octanol-water distribution coefficient (D_{ow}).
- T criteria are the same as in Annex XIII of the REACH Regulation; extra criteria are also considered that specifically address concerns for chronic exposure of the general population via drinking water.

This proposal is applicable to substances currently registered under the REACH Regulation. However, it is also applicable to PTFE (exempted of this legal requirement because it meets the REACH definition of a polymer substance), because this is an identifiable organic substance.

PTFE fulfils the persistence criterion. This substance is highly stable in the environment. It is resistant to thermal degradation, being stable for decades at temperatures up to 260 °C; it is also stable in terms of hydrolysis, oxidation, and light, as well as in terms of anaerobic and aerobic degradation (Henry et al., 2018).

PTFE does not fulfil the proposed mobility criterion by UBA because it is practically insoluble in water and not soluble in octanol. The water solubility of PTFE would be classified as practically insoluble (0.01 µg/L) to very slightly soluble (0.1 µg/L). This means that the water solubility of PFTE is lower than UBA's proposed criteria. Also, PTFE is not soluble in octanol, so it is not possible to measure or calculate the D_{ow} (Henry et al., 2018).

Finally, PTFE does not fulfil the proposed toxicity criterion by UBA because its average molecular weight (MW) is too large to cross a cell membrane, which means it is not bioavailable nor toxic. PTFE has been tested extensively in the US and the EU to assess commercial applications for food

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[6] An updated version of the UBA criteria was published in 2019 which slightly modifies the considerations for PMT evaluation. In any case, it is worth noting that these criteria have not been implemented at EU level.

contact and global medical device regulations (e.g., ISO 10993 biocompatibility tests), and the results demonstrate the absence of toxicity (Henry et al., 2018).

Summarizing, PTFE would not be classified as a PMT substance, given its negligible solubility (not M) and the fact that it has been demonstrated to have no systemic toxicity (not T).

In conclusion, while FPs may meet the REACH definition to be considered persistent, they are not toxic (biologically inert) and not mobile (not soluble in water) and, therefore, they do not present a hazard to biota or the environment.

2.1.2. Hazard assessment

A substantial dataset of scientific information, mainly developed for other regulatory needs as food contact legislation and global medical device regulations, demonstrates that FPs do not pose a significant risk to human health or the environment because of their unique characteristics. In terms of toxicity, there are two categories to address when evaluating hazard: local toxicity and systemic toxicity.

Local toxicity refers to those effects that are observed at the site of first contact, caused irrespective of whether a substance is systemically available. It means that the organ responsible for absorption and elimination may be severely affected. Typical local effects are allergic reactions, irritation and corrosion occurring on the skin, on the eyes, on the respiratory tract or on the gastrointestinal tract. Considering PTFE as a representative substance inside the FPs family, the results of irritation and skin sensitization tests (according to ISO 10993-10 standard) on three different physical samples of this substance (patch, fibre, and tube) were non-sensitizing and non-irritating. Taking these results into account, it can be extrapolated that FPs do not cause local toxic effects (Henry et al., 2018).

Systemic toxicity refers to those effects that are observed in distant locations to the site of first contact, with potential impact at multiple organs. Typical systemic effects are acute toxicity, sub-chronic toxicity, chronic toxicity, carcinogenicity, developmental toxicity, and genotoxicity. Substances that are able to cause systemic effects must be first absorbed into the blood stream, through the alveoli in the lung, across the skin, or across the gut. Bioavailability is strongly related to potential systemic toxicity of a substance.

It is typically accepted that, in general, as MW of the substances increase, bioavailability and toxicity decrease, and that at MW > 1,000 Da, bioavailability is negligible (Kostal, 2016). This means that substances that can be absorbed into the blood must have MW below the limit of 1,000 Da. Also, in the case of the skin penetration of chemical compounds, the general rule is that the MW of a substance must be under 500 Da to allow skin absorption (Bos, 2000). As FPs have very high MW, with most ranging from 100,000 to millions of Da, they cannot cross these barriers (lung, skin, and gut) and, consequently, they cannot be absorbed into the blood. Therefore, FPs are not bioavailable, and they are not capable of producing systemic toxicity.

The position that FPs are too large to penetrate cell membranes is currently questioned considering some new medical developments, as the use of polymer nanoparticles to deliver chemotherapeutic drugs to cancer cells (Lohman et al., 2020). However, it must be considered that this is an application in which FP particles are specifically designed to deliver therapeutic treatment and should not be used as a general rule to question the well-established and documented knowledge about the inability of FPs to cross membranes (unless specifically designed to do so). Moreover, the MW of these nanoparticles range between 12,000 and 21,000 Da, smaller than the typical MW of FPs. In the case of PTFE, this position and the lack of systemic toxicity are corroborated by the results of the tests related to the ISO 10993 standard, performed to guarantee compliance with the global medical device regulations (Henry et al., 2018).

It has been demonstrated that some FPs satisfy the PLC criteria (Henry et al., 2018). While these criteria are not completely agreed worldwide, basic consensus exists around the following (OECD, 2009; Deloitte, 2015):

- Number-average MW (Mn): an Mn of ≥1,000 Da is a generally accepted Mn range for a PLC.
- Content of low MW, oligomeric species (no common levels accorded among global regulations).
- Presence (or absence) of specific reactive functional groups (RFGs) in the polymer: these are functional groups that are known to be associated with toxicity of polymers and include cationic species that are known to result in aquatic environmental toxicity.
- Solubility (in water and other solvents): polymers with water solubilities <10 mg/L showed generally low health concern.
- Other criteria: stability of the polymer, chemical class (or polymer class), residual monomer content and human health hazard classification.

The evaluation of the most representative FPs (Henry et al., 2018) shows that PTFE, ETFE, FEP, and PFA satisfy the widely accepted assessment criteria to be considered PLCs. All of them are high MW polymers, stable against hydrolysis, light, oxidation, and biodegradation, and thermally stable in the range of 150 °C to 260 °C. Also, they are practically or completely insoluble in water and not soluble in octanol. As solubility in octanol is predictive of lipid solubility, FPs cannot dissolve in cell membrane lipids to gain access to cellular contents. Because FPs cannot enter the cells, they are not capable of bioaccumulation or bioconcentration in aquatic life.

In addition, these FPs satisfy the PLC criteria for low MW leachable by-products. Taking into account the information provided by the respondents to the RMOA questionnaire, manufacturers of PTFE guarantee a content of PFOA below 25 ppb, and some DUs have established a limit of 0.25 mg/kg of this kind of leachables coming from the FPs as raw materials in their final FP products.

Furthermore, FPs are not classified as hazardous substances by manufacturers and suppliers (see self-classification in Section 2.1.4), and they are considered as not hazardous to water in some national legislations (e.g., the German Ordinance on systems for handling substances hazardous to water (AwSV, 2017)).

A more recent evaluation (PlasticsEurope, 2020b) demonstrated that PVDF and VDF-co-HFP also fulfil the PLC criteria. This means that the main FPs (accounting for 70-75% of consumption) have been demonstrated to meet the criteria established by the OECD on PLC and as such they do not pose significant risks to human health or the environment. At present time, FPG is working to extend this evaluation to other FPs in order to demonstrate that they are also in compliance with the PLC criteria.

2.1.3. Harmonised classification in Annex VI of CLP

For substances with hazards of highest concern, such as carcinogenicity, mutagenicity, or reproductive toxicity (CMR) and respiratory sensitisation, and for other substances on a case-by-case basis, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management. This is done through harmonised classification and labelling (CLH). Harmonised classifications are listed in Annex VI of the Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) and should be applied by all manufacturers, importers, or DUs of such substances and of mixtures containing such substances. These classifications are legally binding (ECHA, 2021a).

Harmonised classifications can be proposed by a MSCA, or a manufacturer, importer, and DU of a substance, via the submission of a CLH proposal to ECHA. CLH can be proposed for substances without a current entry in Annex VI of the CLP Regulation, or to those with an existing harmonised classification, which would need to be changed either due to availability of new information, new scientific or technical developments, changes in the classification criteria or based on the re-evaluation of existing data.

None of the FPs detailed in point 1.3.4 of this report has an entry and thus a harmonised classification in Annex VI of the CLP Regulation.

2.1.4. Self-classification

Manufacturers, importers, or DUs must self-classify substances to ensure a high level of protection to human health and the environment. Self-classification involves identifying the hazards of the substance and comparing the hazard information with the criteria laid down in the CLP Regulation. Classification is based on intrinsic properties of a substance and not on the likelihood of exposure and risk considerations. It aims to determine whether a chemical substance has physical, health and/or environmental hazards and to allow for a proper communication of these hazards with adequate labelling in the supply chain when the FP product is placed on the market, regardless of the volume of the substance manufactured. This self-classification is also communicated through the Safety Data Sheet (SDS) of the substance. Under CLP, a substance must be self-classified when it has no harmonised classification in Annex VI of the CLP Regulation. Even if a substance is listed in Annex VI to CLP with harmonised classification for a specific hazard endpoint, evaluations and self-classifications are required for all other endpoints, as appropriate.

To derive a self-classification, the manufacturer, importer, or DU must gather all the available information and evaluate its adequacy and reliability, in relation to all possible hazard classes. The information then needs to be evaluated against the classification criteria and the corresponding classification has to be decided. New scientific or technical developments have to be followed, and decisions have to be made on whether a re-evaluation of the self-classification of the substance placed on the market should be conducted.

Some of the respondents to the RMOA questionnaire (mainly FPs manufacturers) have made available the relevant eSDSs for the following materials: PTFE, PFA, FEP, FEPM, FEVE, FFKM, ETFE, PVDF, ECTFE, amorphous fluoropolymer, fluoropolymer ionomer, as well as for some fluoroelastomers and PFPEs. From the analysis of these eSDSs it is concluded that none of these FPs are classified according to the CLP Regulation. This means that the self-classification assigned by the manufacturers of these materials is always given as "Not a hazardous substance".

2.1.5. CLP notification status

The Classification & Labelling (C&L) Inventory is a database that contains basic information on classification and labelling, related to substances subject to the CLP Regulation which has been received from manufacturers and importers. It also contains the list of legally binding harmonised classifications. It was established and is maintained by ECHA.

The FP substances that appear in the C&L Inventory are listed in Table 36 (ECHA, 2021a), including notified classifications and the number of notifiers.

Table 36. Information from the C&L Inventory

FP Substance	CAS number	Classification	Number of notifiers
FEP	25067-11-2	Not classified	10
PTFE	9002-84-0	Not classified	684
		Eye Irrit. 2 (H319)	24
		Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	3
		STOT RE 1 (H372)	1
		Acute Tox. Cat. 4 (H332)	1
PVDF	24937-79-9	Not classified	46
		Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	1
PCTFE	9002-83-9	Not classified	6
VDF-co-HFP / FKM#1	9011-17-0	Not classified	44
		Aquatic Chronic 2 (H411)	14
THV / FKM#2	25190-89-0	Aquatic Chronic 2 (H411)	66
		Not classified	42
PFPE 1	60164-51-4	Eye Irrit. 2 (H319) STOT SE 3 (H335)	100
		Not classified	38
PFPE 3	69991-61-3	Not classified	6
		Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	1
PFPE 5	69991-67-9	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	4
		Not classified	2

It is worth noting that the notification to the C&L Inventory is not controlled by ECHA and the MSCAs. Also, notifications are anonymous and no information regarding the notifier, or the scientific evidence used to support the notified classification is available. For example, a specific classification may be notified on the basis of the impurity profile of a substance as manufactured or used by a specific company, but this may not be representative of the substance on its own, or for the majority of manufacturers or users. This means that, in practice and although ECHA encourages notifiers to agree on classification, the classifications notified for a substance cannot be disputed. While they can be considered for regulatory purposes, indications from the C&L inventory should be handled with caution.

All FP substances have received at least one notification as “Not classified”, in line with self-classifications, as provided in the SDS. Furthermore, FEP and PCTFE only receive notifications as “Not classified”. In all cases except for three substances (THV, and substances with CAS number 60164-51-4 and 69991-67-9), “Not classified” is the entry with the largest number of notifiers.

Most of the classification entries are related to local toxicity effects (skin and eye irritation). In the case of PTFE, this classification is not in line with the results of the specific tests performed on this material, as commented in Section 2.1.2. Also, as PTFE is a well-known representative of the FPs family, these classifications could be disputed for the other materials. As per classifications related to systemic toxicity and environmental effects, which are reported by a very low number of notifiers in comparison with other entries, they could be contested considering all the information provided in Sections 2.1.1 and 2.1.2.

2.2. Information on volumes and uses.

2.2.1. Tonnage

As FPs are exempted from the legal obligation to register under the REACH Regulation, no official information about tonnage manufactured and imported for these substances in the EU can be found in the ECHA website. Therefore, the information available on tonnage of FPs is that provided by the industry. However, the responses received to the RMOA questionnaire do not allow for an accurate estimation of these volumes, since not all manufacturers, importers and DUs of FPs have responded to it, and the quality of some of the responses received is not adequate (e.g., some respondents have not replied on the grounds of confidentiality, or only broad ranges have been provided). For this reason, the most accurate available information on tonnage of FPs is that included in the SEA commissioned by the FPG (PlasticsEurope, 2017). This information is detailed in Section 2.4.

2.2.2. Overview of Uses.

As previously commented, due to their unique properties, FPs are involved in many uses and applications. Some of the markets in which FPs are used have evolved significantly in the last years, and they are considered critical for the development of the future EU strategies and societal sustainability goals.

The most important applications of FPs are the following:

- Transport (including automotive, aircraft, rail, marine, and aerospace industries).
- Chemicals (including chemical and industrial polymerization (machinery), lubricants and greases, hydraulics, mining, and additives).
- Power (including oil, gas, and conventional energy industries).
- Cookware (including glass coatings industry).
- Electronics (including semiconductors industry).
- Food processing, food packaging.
- Pharma.
- Textiles.
- Architecture (including construction and building industries).
- Medical applications.
- Renewable energy (including photovoltaic (PV), solar applications, wind turbines, lithium-ion batteries, fuel cells and hydrogen technology industries).
- Other uses (including water treatment, consumer products, printing inks, organic electronics, and cosmetic packaging).

Information about these uses is extensively detailed in Section 2.4.

Considering these applications and the replies received from manufacturers and DUs to the RMOA questionnaire, the specific uses of each of the substances detailed in Section 1.3.4 is described in the following table:

Table 37. Overview of uses per substance.

Substance	CAS number	Transport	Chemicals	Power	Cookware	Electronics	Food	Pharma	Textiles	Architecture	Medical applications	Renewable energy	Others
ECTFE	25101-45-5	X	X	X		X		X		X		X	
ETFE	25038-71-5 / 68258-85-5	X	X	X	X	X	X	X		X	X	X	
FEP	25067-11-2	X	X	X	X	X	X	X		X	X	X	
PFA	26655-00-5 / 31784-04-0	X	X	X	X	X	X	X	X	X	X	X	
PTFE	9002-84-0	X	X	X	X	X	X	X	X	X	X	X	X
PVDF	24937-79-9	X	X	X		X	X	X	X	X	X	X	X
P(VDF-TrFE)	28960-88-5					X						x	
PCTFE	9002-83-9		X			X	X	X					
EFEP	Confidential	X	X			X	X						X
CPT	-	X				X							
VDF-co-HFP / FKM#1	9011-17-0	X	X	X		X	X	X		X	X	X	X
THV / FKM#2	25190-89-0	X	X	X	X	X	X	X	X	X	X	X	X
VTP / FKM#3	56357-87-0	X	X	X		X	X			X			
FFKM	26425-79-6	X	X	X	X	X	X	X					
FEPM	27029-05-6	X	X	X		X	X				X		
VDF/HFO-1234yf	1034381-22-0	X											
TFE/E/HFP/PMVE /VDF	149935-01-3	X											
TDM	870707-45-2	X		X						X			
PFPE 1	60164-51-4	X	X	X	X	X	X	X	X	X	X	X	
PFPE 2	113114-19-5	X											
PFPE 3	69991-61-3	X	X	X	X	X	X	X	X	X	X	X	
CAS 185701-88-6	185701-88-6	X											
PFPE 4	370097-12-4	X	X	X	X	X	X	X	X	X	X	X	
PFPE 5	69991-67-9	X	X	X	X	X	X	X	X	X	X	X	
FEVE	146915-43-7 / 207691-69-8	X				X				X		X	
FP ionomer	-	X	X	X		X					X	X	
FP amorphous	101182-89-2		X			X					X		

2.3. Exposure, releases, and risk

The main information related to exposure, releases, and risk of a substance is submitted by industry through the Chemical Safety Report (CSR) that is part of the REACH registration dossier. Most of this information is not publicly available, but it helps ECHA and the MSCAs to understand and evaluate the effects that a substance could have on human health and the environment. The public part of this information is the Exposure Scenario (ES), defined for each use of the substance, that must be included in the extended Safety Data Sheet (eSDS) and delivered to the relevant actors in the supply chain. The ES contains all the recommended Risk Management Measures (RMMs) and Operating Conditions (OCs) that are considered to be relevant by the registrant for each specific use of the substance, in relation to ensuring adequate control of risks for both human health and the environment. RMMs and OCs are focused on the minimization of human exposure and environmental releases of the substance, through the implementation of actions, procedures, and systems that may include, among others, general and local exhaust ventilations, effluent treatment in wastewater treatment plants, use of air emission abatement equipment, or use of personal protective equipment.

However, since FP substances are exempted from the obligation to register under REACH, information on uses, exposure, releases, and risk is not available from registration dossiers. In addition, due to lack of CSRs and ES, no specific recommendations on RMMs and OCs are easily accessible.

As previously discussed, FPs are considered to be persistent substances, but the persistence property on its own does not imply that there is a present or future risk. As described in Section 2.1.1, FPs are not toxic (biologically inert) and not mobile (not soluble in water); therefore, although they are persistent, they do not pose a hazard to biota or the environment. Furthermore, as described in Section 2.1.2, FPs do not cause local toxicity effects, they are not capable of producing systemic toxicity, and some of them, which correspond to the majority of volume in terms of manufacture and use, meet the criteria established by the OECD to be considered as PLC. Finally, as detailed in Sections 2.1.3, 2.1.4, and 2.1.5, these substances do not have harmonized classification in Annex VI of the CLP Regulation, and the companies that manufacture FPs self-classify them as “Not classified”, which is the most typical classification notified to the C&L Inventory.

For all these reasons, it might be considered that the assessment of exposure, releases and risk of FP substances is not necessary. However, indications from some regulators and part of the scientific community suggest that FP products should be assessed in a life-cycle perspective, including substances that are used during the manufacturing process, and the by-products generated at end-of-life stage (ECHA, 2020).

The manufacture of some FP products is intimately linked to the use of certain PFAS as polymerization aids. Residuals of these polymerization aids and solvents, but also of some monomers, oligomers, and other by-products generated during the polymerization process could be emitted during the manufacture, polymerization, use, and end-of-life treatment of FP products. Furthermore, there are additional questions regarding the safe disposal of articles that contain FPs at the end of their life-cycle. Therefore, while it can be argued that there is no reason for concern on FP substances themselves, it is relevant to assess the impacts of FP products and articles containing FPs, and their associated residual substances (polymerization aids, monomers, oligomers, and other by-products) on human health and the environment, as well as their disposal at the end of the life-cycle.

As mentioned previously, some types of FPs that are manufactured via an emulsion polymerization reaction require the use of polymerization aids, utilized as dispersants, surfactants, and emulsifiers, in order to favour the intimate mixing of the monomers to complete an efficient and safe polymerization reaction and to meet stringent specifications. According to some available scientific literature (Henry et al, 2018; Lohman et al., 2020) the substances historically used as polymerization aids in the manufacture of FPs have been low-molecular-weight non-polymeric PFAS, such as PFOA and perfluorononanoic acid (PFNA). Some literature has found these substances to pose potential hazards to health and to the environment at high concentrations. For this reason, the leading global FP manufacturers have implemented strategies to replace these polymerization aid. Industry voluntary initiatives such as the PFOA Stewardship Program of the US EPA (US EPA, 2006) or the restriction of PFOA and its related salts in the EU REACH (ECHA, 2017) and PFCA C9-C14 in the EU REACH (ECHA, 2021b) were the starting point for the transitions.

The responses provided by the FP manufacturers to the RMOA questionnaire reflect the different approaches, with the majority of companies declaring the continued use of substances belonging to the PFAS family as polymerization aids, some companies reporting use of PFAS as polymerization aids depending on the type of FP product or grade of interest[7], and other companies informing that they are not using PFAS anymore as polymerization aids (or are proceeding with a complete elimination in the coming years). It is important for an assessment of this feedback that not all companies manufacture all FP products and that not all FPs can be manufactured without PFAS polymerisation aids, because this could be application dependent. Some companies are more specialized than others which leads also to different outcomes in their approach to the viability of non-PFAS polymerization aid technologies.

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[7] It is worth to noting that, depending on the grade of purity required of the FP product (derived from the safety and performance requirements of the supply chain), at this moment it is not technically possible to completely remove PFAS as polymerization aids from the manufacturing process. Therefore, this possibility will depend on the FP product portfolio managed by each FP manufacturer.

In parallel to these replacement strategies, the FP manufacturers have implemented containment and recycling strategies in order to capture, recover, remove, purify, and recycle the polymerization aids from off-gases, waste-water streams, aqueous dispersions, and also reduce or remove from the final FP products. These recovery/recycling techniques are suitable for a variety of polymerization aids, including a variety of PFAS (Dams et al., 2016). However, it cannot be ruled out that very small residual concentrations of these substances would be found in the final FP products.

The presence of monomers, oligomers[8], and other by-products in the final FP products depends on the degree of completion of the polymerization process. Since it is not realistic to expect that a polymerization reaction will reach 100% completion, the presence of this kind of residual substances (even if in very small proportion) should always be expected in the FP products. If these residuals are leachable (they may be able to migrate out of the FP products) and if they have low MW (lower than 1,000 Da), therefore they could potentially cross cell membranes and enter the blood stream. This is the main concern related to the presence of these residuals in FP products.

According to the responses to the RMOA survey, manufacturers of FPs are aware of this concern and some of them have implemented strict procedures throughout the manufacturing process to eliminate or minimise these residuals from the FP products. The residuals are removed and recovered (in the case of free monomers) at the end of the polymerization process. However, it cannot be ruled out that they are present at trace levels in the final FP product.

FPs are used as raw materials in a wide range of industrial manufacturing sectors. The Safe Handling Guide provided by Plastics Europe (PlasticsEurope, 2012) and the SDS provided by the manufacturers provide general use guidelines. However, each processor has to adhere to applicable regulations, assess their own process and local industrial hygiene guidelines. No detailed information about exposure, releases, and risk during DU processing could be readily compiled for each one of those sectors. FPs themselves are processed or formulated at industrial facilities and most of the uses are industrial as well.

There are no direct consumer or professional uses of FPs substances. FP products for consumer and professional uses are commonly contained in articles. The levels of exposure and emissions will depend on the FP product form and the degree of containment of the FP products in the articles manufactured. If FP products are well embedded in a matrix (e.g., plastic material, coating of metals for cookware, coatings for glass, etc.) the exposure and release will be low or insignificant. But if these articles are not properly manufactured or used, this can increase the potential for exposure and emissions.

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[8] Oligomers are defined as small polymers with up to about 100 monomer units (Lohman et al., 2020).

2.3.1. Worker exposure during the manufacturing process

Exposure to FP substances should not be considered a concern for human health because they do not cause local toxic effects and they are not capable of producing systemic toxicity. However, in a life-cycle perspective, concerns derived from the presence of residuals (polymerization aids, solvents, monomers, oligomers, and other by-products) in the final FP products need to be considered in a risk assessment throughout the supply chain.

In this case, it is worth to note that manufacturers of FPs are continuously making efforts to avoid the use of substances (such as PFOA, PFNA or PFOS) that have generated concern over the past years due to their toxicity profile, and for which regulatory actions are already in place. Related to the use of other PFAS as polymerization aids, for which a harmonized hazard profile is currently not available, there are two important facts to take into account:

- These substances are used in a very low concentration in comparison to the total quantity of FPs manufactured (Buck et al., 2011).
- According to the responses to the RMOA questionnaire, all the manufacturers of FPs have implemented occupational health and safety management systems that include monitoring of the employees involved in the manufacturing process of FPs, according with legal and applicable requirements, as well as the implementation of control systems.

Related to the amount of polymerization aids in use, it is very unlikely that exposure to these very low levels of PFAS could lead to health risks. However, the level of risk also depends on the duration of exposure and on the severity of the hazard, and these factors can be controlled considering that manufacturers of FPs operate occupational health and safety management systems in compliance with (or based on) international standards (ISO 45001, OHSAS 18001), that provide a framework to increase safety, reduce workplace risks and enhance health and well-being at work. These management systems also include the regular performance of occupational exposure monitoring and training programs for the workers.

In order to supplement the lack of legal exposure limits of certain PFAS, some manufacturers of FPs have defined their own in-house exposure limits to verify that exposure to workers is controlled. Some of the responses to the RMOA survey provided by manufacturers of FPs indicate concentration of fluorinated surfactants below 0.01 mg/m^3 at 8-hour TWA (time-weighted average).

In addition, control methods have been implemented at manufacturing sites to avoid exposure of workers to PFAS polymerization aids and other potential hazardous substances used in the manufacturing process. These methods range from general engineering controls (automated manufacturing process in closed systems, general and local exhaust ventilation, physical separation such as curtains between areas, ventilated booths), to personal protective equipment (respiratory protective equipment, dermal and eye protection such as face masks, safety glasses, gloves, and protective clothing, and general hygiene procedures). These industrial processes and procedures are continuously improved as the state of the art of these techniques evolves and new technologies become available on the market.

In the case of the manufacturers of FPs that have eliminated the use of PFAS as processing aids, no exposure is considered, neither during the manufacturing process nor later in the supply chain. However, the possibility that certain PFAS by-products may be generated due to unintended reactions between non-PFAS polymerisation aids and fluorinated monomers in the reaction process should be taken into account. Nevertheless, it is worth noting that these companies have also implemented occupational health and safety management systems to monitor and control the manufacturing steps.

Regarding DUs, given that PFAS polymerization aids are used in a very low concentration in the manufacturing process of FP products, the residuals in the raw materials that they handle can be estimated down to ppm or even ppb levels. Furthermore, the implementation of recovery/recycling techniques for polymerization aids within the manufacturing process by some manufacturers of FPs, with an overall recovery rate for PFAS of approximately 98% (Dams et al., 2016), indicate that the level of residuals in the FP products coming from the PFAS polymerization aids will be very low.

For these reasons, and in the case of solid FP products, manufacturers do not expect significant exposure levels for workers at DU sites when handled according to information provided by the supplier (e.g., on the SDS), as expressed in some of the replies to the RMOA questionnaire. In the case of liquid FP products, and according to the responses of the DUs to the RMOA survey, the usual specification provided by the manufacturers of the commercial FP products are typically below 1 ppm. Furthermore, in the case of FPs manufactured without PFAS polymerisation aids, exposure to PFAS through the supply chain will be non-existent, as long as no PFAS residuals are generated during the manufacturing process, either as by-products or via presence of free monomers.

Only some of the DUs that have provided replies to the RMOA survey have indicated that they have occupational health and safety management systems in place, including regular occupational exposure monitoring on-site for processes involving FPs. This is due to the wide range of industrial sectors that use FPs, including large, medium, and small sized companies. In some cases, occupational monitoring is reported as a legal obligation, but not specifically related to PFAS (monitoring of respirable/inhalable dust).

As previously discussed, the presence of residuals (polymerization aids, monomers, oligomers, and other by-products) resulting from the polymerization reaction process is another concern related to human health, because these chemicals are not bound to the FP products (i.e., they can be leached from these FP products) and, depending upon their structure, they can become bioavailable (i.e., they can cross cell membranes). However, it is important to point out that the most relevant FP products on the market (PTFE, ETFE, FEP, PFA, PVDF, and VDF-co-HFP) easily meet the PLC criteria. The PLC criteria (OECD, 2009; Deloitte 2015) include, among others, limits to the content of low MW leachables and to the proportion of oligomers with MW < 1,000 Da and, according to the scientific data (Henry et al., 2018; PlasticsEurope, 2020b), these FPs comply with both criteria. The content of oligomers is negligible in most of the cases and the content of low MW leachables is lower than 1 ppm in the case of PTFE and below quantification limits in the other cases. This is due to the post-polymerization steps (washing, heating, etc.) implemented by some of the manufacturers of FPs, which allow for the removal of residuals from the final commercial FP products. Therefore, no relevant exposure is expected for workers involved in post-manufacturing processes (formulation, packaging, etc.). For workers involved in the manufacturing process of the DUs, engineering controls, spot ventilation and PPEs can be relevant as described in the Safe Handling Guide for Fluoropolymers (PlasticsEurope, 2012).

Regarding the other FP products, which have not yet been fully assessed under the PLC criteria, the content of residuals can be considered very low as well, because the manufacturing process includes the same post-polymerization polymerization steps (washing, heating, etc.) to remove them. According to the responses to the RMOA questionnaire, the specification provided by the manufacturers of FPs for the commercial FP products establishes levels of residuals below 0.1% (purity of FP products >99.9%). This information is consistent with the eSDSs provided by the manufacturers of FPs. According to the responses to the RMOA questionnaire, some DUs have established a limit of 0.25 mg/kg for this kind of leachables from the FP products used as raw materials in their manufacturing process.

2.3.2. Releases/emissions in the manufacturing process

Similar to the rationale used for human exposure, FP substances themselves should not be considered a concern for the environment because they are not PBT substances (although they are persistent, they are biologically inert and not toxic) and not mobile (not soluble in water). However, considering the complete life-cycle of FPs, environmental concerns derived from the use of specific PFAS as polymerization aids during the manufacture of FPs, and from the presence of leachable residuals (polymerization aids, monomers, oligomers, and other by-products) in the final FP products that are used by the DUs in their own manufacturing processes should be taken into account.

The companies that manufacture FPs recognize that specific PFAS and leachable residuals emissions can occur during the manufacturing process and downstream use of FP products, as mentioned in some of the replies to the RMOA questionnaire. As a result, companies implemented processes to reduce and manage emissions. For example, there is evidence that the drying step of FP products has historically led to emissions to air of PFAS polymerization aids at PTFE manufacturing sites (Lohman et al., 2020). Also, a report to the Nordic Council compiled historic release estimates for other types of FPs (Wang et al., 2020)[9]. According to the literature (Lohman et al., 2020) the different ways of emissions to the environment can be listed as follows:

- Release of specific PFAS from their use as polymerization aids in the manufacture of FP products.
- Release of leachable residuals during the processing of FP products. Some of these leachables can be fluorinated by-products even if no PFAS are used as polymerisation aids.
- Release of residuals from processing of FP products by DUs in suspension/liquid form.

The main concern related to the emissions of non-polymeric PFAS used as polymerization aids in the manufacturing of FP products is that their environmental behaviour could be similar to that from legacy polymerization aids (e.g., PFOA, PFNA) which are currently restricted or in the process to be restricted: they are expected to persist in the environment, may bioaccumulate, and may be highly toxic (Henry et al., 2018). Regarding the leachable residuals (monomers, oligomers, and other by-products), the main environmental concern is that, as they are not bound to the FP products, they may be released to air upon heating during manufacture and to water through wastewater streams (Lohman et al., 2020). Furthermore, some of these residuals are highly volatile due to their low MW and, therefore, they can be released to air at low temperatures. Finally, some FP products are marketed in the form of suspensions that contain submicron FP particle sizes. Thus, release of bioavailable particles during the use of these materials by the DUs, mainly to the wastewater streams, is possible (Lohman et al., 2020).

The companies involved in the manufacture of FPs are aware of these environmental concerns, and they are committed to the reduction of air and water process emissions. Following the responses to the RMOA questionnaire provided by manufacturers of FPs, it is confirmed that all of them have implemented environmental management systems, including the monitoring of emissions, and the implementation of Best Available Techniques (BAT) in the manufacturing process of FPs. Most of these companies have defined Corporate Environmental Commitments

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[9] According to the information provided by the FPG members in the replies to the RMOA questionnaires, the manufacturing process of FPs are continuously improved, which may render the use of historic data on emissions obsolete.

that go beyond the environmental management of emissions related to the manufacture of FP products.

Due to the concerns generated by potential emissions of specific PFAS, limits are defined at different levels (mainly local and regional, but also national in some cases), and these releases are strictly controlled. All the EU FP manufacturing sites operate under environmental permits in accordance with national and regional legislations, transposing the European Directive 2010/75 on industrial emissions (integrated pollution prevention and control), that defines the environmental limits and conditions for the manufacture of FP products.

As an example, permit requirements for plants operating in the Netherlands are in place, related to air emissions of specific PFAS (450 kg/y), direct surface water emissions (5 kg/y), and indirect emission to a local wastewater treatment plant (140 kg/y). In this case, and according to the current trend to restrict releases as much as possible, in 2020 the limit was reduced by Authorities to the current value from 2,000 kg/y in 2018 and 6,000 kg/y in 2017. Indeed, the company that operates sites in the Netherlands have publicly informed that their total emissions (air and water) have been reduced from more than 8,000 kg/y in 2013 to less than 50 kg/y in 2021 (expected). In general, all the manufacturers of FPs have declared in their replies to the RMOA questionnaire that they are complying with the limits imposed in their environmental permits. Furthermore, companies that have reported their current emission values in the survey are informing of total emissions of fluorinated substances in the order of hundreds of kg/y as maximum. Finally, some manufacturers of FP products have informed that they focus their monitoring actions on the control of Volatile Organic Compounds (VOCs), that are related to emissions of the volatile residuals contained in the FP products.

Companies that manufacture FPs operate environmental management systems in compliance with (or based on) international standards (ISO 14001, RC 14001), that provide a framework to reduce emissions and increase protection to the environment. These management systems include the regular performance of environmental exposure monitoring and training programs for the workers. Moreover, some of the companies have reported that their environmental management systems are in compliance with the European Regulation 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), which is considered to be the most robust environmental program for European companies in this field.

Regarding BAT, while there are no specific techniques detailed for FPs, compliance with general BAT requirements for the manufacture of polymers (BREF, 2007) and the common wastewater and waste gas treatment/management systems in the chemical sector (BATC, 2016) are in place. Manufacturers of FPs have implemented this kind of technologies to contain and control the environmental emissions, and they are continuously improving these processes with new technologies as they become available on the market. Investments in BAT are in the order of tens of millions of euros (per company) in recent years, and more improvements are planned in the coming years.

Following the responses to the RMOA questionnaire with industry, the following list provides detail on the BAT implemented at the FP manufacturing sites:

- Water and wastewater emissions:
    - Physical separation
    - Chemical precipitation
    - Stripping
    - Filtration
    - Ion exchange (IE)
    - Granular activated carbon (GAC)
- Air emissions:
    - Caustic scrubber
    - GAC
    - Regenerative thermal oxidation (RTO)
- VOC emissions:
    - Filtration
    - Caustic scrubber
    - GAC
    - RTO
- Dust (solid particles) emissions:
    - Filtration
- PFAS polymerization aids emissions (additional to the BAT listed above):
    - Specific recovery/recycling techniques (rates over 98%)
    - Incineration

However, there are some concerns about the BAT related to abatement of emissions from FP manufacture (Lohman et al., 2020), specifically related to highly volatile fluorinated by-products with potential for environmental and, indirectly, for human exposure. These are difficult to remove in filters or liquid scrubber baths. For this reason, the releases of these residuals, mainly generated during the drying and sintering steps, are treated through combined techniques (caustic scrubber, GAC, and RTO).

As previously mentioned, all the members of the FPG have defined Corporate Environmental Commitments. These programs are typically detailed in their websites, and they include compromises around a variety of topics such as greenhouse effect gases, water consumption reduction or circular economy, in accordance with the main EU policy objectives.

Regarding DUs, a limited number of companies that have answered the RMOA survey have indicated that they have environmental management systems in place, including regular environmental exposure monitoring on-site for processes involving FPs. Furthermore, not all of them have environmental permits in place and, for this reason, they have no legal obligation to perform environmental measurements, although most of them are in a position to do this wherever relevant. Finally, only a few DUs have implemented BAT in their manufacturing processes. As in the case of human exposure, this is due to the wide variety of companies and industrial sectors involved in the supply chain of the FPs products.

2.3.3. Disposal of FPs

Concerns related to disposal of FPs, as the final step of the life-cycle for these materials (end-of-life), are not typically related to the FP substances themselves. This is justified by the low degradability potential of FPs under environmental conditions, as has been commented in Section 2.1.1. (OECD, 2018).

Regarding disposal of waste generated at sites in which FPs are manufactured, the typical treatment processes that are used are the following (PlasticsEurope, 2012):

- Solid waste containing PFAS polymerization aids is collected for disposal and incinerated, internally or by an approved waste disposal company.
- Solid waste not containing PFAS polymerization aids is collected for disposal by an approved waste disposal company and landfilled as non-hazardous waste.
- Water emissions are collected, the solid content is separated (by precipitation and decanting or filtering), and the liquid is treated at a water treatment plant, onsite or municipal.

Regarding recovery of FP products to avoid disposal, there are different techniques for waste treatment, focused on recovery of the solid waste. In the case of FP products that have been manufactured using polymerization aids, the first step of this recovery process is the removal of these substances from the waste of the FP products, following the same techniques used in the case of the commercial FPs. As previously discussed, these techniques have an overall recapture rate of approximately 98%. The recovered polymerization aids can be recycled and re-used in the manufacturing process, or they can be destroyed by incineration.

Once the solid waste is clean there are three main possible recovery treatments (Schlipf and Schwalm, 2014; Pro-K Fluoropolymergroup, 2018):

- Primary recycling: solid waste is ground and later fed back into the manufacturing cycle of FP products. This recovered material is mainly used in the manufacture of low performance FP products.
- Secondary recycling: solid 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. The recovered material can be used in the manufacturing of new low performance FP products.
- Tertiary recycling or Up-cycling: solid waste is ground, then decomposed into the starting monomers at temperatures above 600 °C (pyrolysis) in order to obtain the same chemical components from which the FP were manufactured; monomers are cleaned by distillation, which can be used to manufacture new FPs with no loss in performance.

The first two recycling treatments can be undertaken by the manufacturers of FP themselves (onsite), or at a larger scale, mainly by specialist recycling companies. These techniques can also be applied by DUs for the recovery of their manufacturing waste, but this option is limited, due to the presence of fillers, colorants, and other materials in the composition of their final articles (PlasticsEurope, 2012). The up-cycling treatment is applicable to some articles containing FPs, such as pipe liners in chemical plants, as well as other plant components like pumps, tank liners, seals, hoses, compensators and many other FPs components and systems (Schlipf and Schwalm, 2014). It needs to be co-located to a FP manufacturing plant.

As previously commented, recycling of FP products and articles containing FPs is difficult because separation of the single components is not always possible, neither in the FP compound nor in the processed finished articles (Pro-K Fluoropolymergroup, 2018). This is due to the fact that FPs are used predominantly in small components of larger finished articles involving a wide variety of materials.

In 2019 FPG sponsored so far unpublished study (PlasticsEurope, 2021a), which involved an analysis of the FP waste in the EU and the different treatment options. The main conclusion of this study was that FPs have an overall small share by mass in the typical post-consumer waste streams, due to FPs affected waste streams (basically industrial) not being in line with the typical plastic post-consumer waste streams, such as residual household waste or separate collected packaging waste. This is because the largest sources of FP waste are the chemical industry and end-of-life vehicles (75% of the total FPs waste). However, the presence of FPs is not a barrier to recycling the main component of the articles containing FPs, e.g., the re-smelting of steel articles (as non-stick frying pans) containing small amounts of FPs, in order to recover the metal (PlasticsEurope, 2012). In this case, there are doubts on whether the potential emissions related to the breakdown of the FPs in the metal smelters at high temperatures are being considered and controlled (Lohman et al., 2020).

Disposal of FP products and articles containing FPs by landfilling can be considered when separation of FPs from the other components is not practical. This technique is considered safe because FPs are persistent and, consequently, inert, and very stable substances (PlasticsEurope, 2012). However, contamination of the soil and the groundwater by leachable residuals contained in the FP products and articles containing FPs (as PFAS polymerization aids, monomers, oligomers, and other by-products) cannot be ruled out, if these residuals have not been adequately treated/removed during the manufacturing process. It is estimated that approximately 15% of the total FP waste is landfilled in EU (PlasticsEurope, 2021a).

The remaining option for the disposal of FP products and articles containing FPs, if the separation of their components is not affordable, is incineration. The largest share of FP waste is thermally treated, with over 80% going through incineration with energy recovery in Western Europe (PlasticsEurope, 2021a), avoiding the consumption of virgin combustible material for the generation of energy. This technique eliminates chemicals by breaking them down at high temperatures, from minimum of 800 and upwards of 1400 ºC. Although FPs are thermally stable at normal temperatures of use, they decompose at high temperatures into hydrogen fluoride (HF), carbon monoxide (CO), and carbon dioxide (CO_2). However, it is to be noted that greenhouse gases such as CF_4 or C_2F_6 could also be generated (Huber et al, 2009).

While there is data available showing that PTFE does not generate PFAS during incineration (Aleksandrov, 2019), control measures may be necessary to maintain emissions from other hazardous substances generated in the process below the limits specified by national or local regulation, e.g., wet scrubbing with caustic solutions to control the emissions of HF (PlasticsEurope, 2012).

In conclusion, the total effect of this disposal technique on the environmental EU policies should be evaluated.

2.4. Socio-economic information

In 2017, the FPG commissioned a SEA of the sector (PlasticsEurope, 2017). The main information related to the socio-economic relevance of FPs contained in this section is extracted from this work, however this has been reinforced and updated with the replies received from the questionnaires that were delivered to the FPs supply chain in the EU, in preparation of this RMOA.

The starting point of the value chain (sales of FPs in their basic form) is relatively small in comparison to the wider socio-economic benefits created by downstream FP applications, which are described below. However, even the manufacture and sale of FPs themselves creates significant direct socio-economic effects in the EU. According to the FPG SEA, in 2015 around 52,000 tonnes of FPs worth around €780m were sold. By tonnage, the EU is a net importer of FPs, but the sales values of exports (€380m) are around 18% higher than the sales value of imports (€310m).

The EU FP manufacturing sector is a highly innovative one, with an estimated €43m invested in Research and Development (R&D) in 2015. This equates to 5.5% of turnover; around triple the EU average. The location of the FP industry in Europe plays an important role in allowing EU-based customers to meet lead times for the various end user sectors. This is necessary in maintaining innovation and R&D, as companies are continually customising FP products for their local customers.

Table 38 provides further details of the main findings of the FPG SEA.

Table 38. Key economic figures for FPs in Europe (2015 data).

FP manufacture in EU (2015)	51,000 tonnes
Volume of FPs exported from EU	20,500 tonnes
Value of FPs exports from EU	€380m
Volume of FPs imported into EU	21,500 tonnes
Value of FPs imports into EU	€310m
Volume of FPs sold in EU	52,000 tonnes
Value of FPs sold in EU	€780m
Direct employment	2,200 jobs
Estimated indirect employment	ca 20m jobs
R&D investment by FP manufacturers in EU	€43m (5.5% of total revenue)

While the information provided is representing the FP market in 2015, more recent estimations provide figures of use of FPs in the EU in the range of 63,000-64,000 tonnes in 2018 (AGC Chemicals Europe, 2021), which results in an approximate 22% increase (7-8% increase per year) in comparison to the 2015 figures. It is to be underlined that this RMOA does not intend to perform a detailed evaluation of the market situation of FPs at present time, however these numbers provide a good orientation on the level of direct economic impact from this industry, with expected significant growth opportunities over the coming years.

FPs are well-known for exhibiting many specific properties, which provide numerous advantages in a large range of products and applications and render FPs as highly valuable products that are used in a wide variety of end uses. FPs enable significant advances in areas such as aerospace, electronics, automotive, industrial processes (e.g., chemical and power sectors, including renewable energy), architecture, food, pharmaceutical and medical applications. FPs are inert materials that are resistant to virtually any chemical, which renders them some of the most versatile and valuable plastics available. It is to be noted that FPs are an expensive class of polymers and usually selected as a last option when all other non-fluorinated alternatives have been assessed and cannot be used to meet the performance requirements.

Some of the key properties of FPs (PlasticsEurope, 2021b) are[10]:

- Inertness and non-reactivity; high resistance to corrosion and to chemical attack makes FPs extremely useful in many industrial and professional environments with very demanding chemical conditions. FPs are not eroded by acids, alkalis, oxidising agents, organic solvents; fluorine gas, chlorine trifluoride, and molten alkali metals are the only chemicals that may erode FPs.
- Low and high temperature resistance: from -200 °C to +260 °C for PTFE and PFA, with other elastomers offering a range of -40 °C to +230 °C.
- Very low coefficient of friction to any solid and excellent dynamic properties, including low surface energy.
- Low and ultra-low permeation rates, allowing for creation of semipermeable/barrier structures.
- Ultraviolet radiation (UV) resistance, in parallel to high optical transparency (excellent transmission of visible spectrum light), leading to long working life in outside environments.
- Excellent electrical insulation, low dielectric constant, and low variations of conductivity.
- High level of fire safety; no flame propagation and low smoke generation; FPs will burn when exposed to flame, but they will generally self-extinguish when flame is removed.
- High and ultra-high purity with extremely low leach out properties.

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[10] While most of these properties are applicable to all FPs, some of them may be relevant only for a selected group of FPs.

- High abrasion, stress-crack, and cut-through resistance.
- Biocompatibility, durability, and flexibility, rendering FP critical for applications in medical devices.
- Mould release films for epoxy in a carbon fibre/epoxy composite laminate.
- Cut resistance, making FPs ideal for high vibration applications like e.g., helicopter wiring.
- Long-term compression resistance of fluoroelastomers.
- Hydrophobicity; neither water nor water-containing substances wet FPs, providing excellent repellent properties to many chemicals.
- Non-stick, and consequently non-fouling properties, along with sufficient bonding in certain multilayer applications.

In relation to the criticality of the use of FPs in the supply chain, replies to the survey that was issued to the DUs of FPs revealed that for 98% of the respondents, at least 1 of the FPs that is used is regarded as “important” or “extremely important”, with 89% of replies highlighting at least one FP as “extremely important”. The justification of these replies is always based on the fact that no other material is available on the market that would meet their customers’ demands in terms of performance, i.e., there is no suitable alternative covering the full spectrum of characteristics that FPs provide to the specific use. Respondents claim that their businesses are highly dependent on the availability of FPs. Only 1 out of 44 replies analysed informed that the FPs may not be important for a specific use, whereas another single reply listed the FPs as important but with potential alternatives that could be available. In this line, more than 2/3 of the replies indicated that their customers would not accept alternatives that would lead to reduced performance. Those replies underlined that the real issue at stake would not be a reduction in quality, but a total lack of feasibility of continuing the business, due to the application not working properly for the specific requirement. Indeed, a significant number of respondents (20) to the survey reported that they would expect facing costs ranging from hundreds of thousands of euros to unpredictable costs due to closure of business. In many markets, a substantial increase in costs would be related to the need for testing, registration, re-design, and certification of new articles, including administrative tasks and support from third parties. More detail on the replies from the respondents to the questionnaires can be found on Annex III.

Table 39 describes the main sectors of use linked to FPs, providing indications of total volume and revenue from sales to key industrial sectors in 2015 (PlasticsEurope, 2018).

Table 39. Volume on Revenue of FPs in the EU (2015 data)

Sectors	**Volume (t)**	**Revenue (m€)**	**Additional relevant information**	
Transport	18,500	300	> 13m employed	Fluoropolymer fuel hoses enable fuel savings and reduce damage from emissions, worth ~ €140m per year in EU
Chemicals & Power	16,500	220	Nearly 3m employed	Corrosion prevention saving hundreds of millions of € each year in the EU
Cookware	3,500	60	Manufacture value in the order of €2 billion	Easy clean non-stick properties, allows cooking with less fat
Electronics (including semiconductors)	3,500	40	EU semiconductor market worth circa €25 billion	Critical in semiconductor manufacturing, enabling progress in IT that has generated trillions of € globally in the last 20 years
Food & Pharma	3,000	40	Nearly 5m employed	Safer and cheaper food and pharma by preventing contamination and material failure
Textiles & Architecture	3,000	40	> 2m employed	Enabling novel and unique 'landmark' architectural designs
Medical applications	1,500	20	Europe accounts for 41% of global medical device patents	Reduces the risks of failure, cross-infections and clogging of medical equipment
Renewable energy	500	<5	Europe leading the global market in installed capacity	PV module manufacture efficiency increases which save €40m – €90m each year in the EU
Other	2,000	30		
Overall	**52,000**	**780**		

The key sectors of use outlined in Table 39 are described in more detail next.

2.4.1. Transport

In automotive applications, FPs prolong the useful life of various critical components for performance, emission control and safety. They provide durable and effective protection against heat, aggressive oils and fuels, humidity, vibrations, and compression. This contributes to increased reliability and durability of parts, and therefore to a reduction in both the cost and extent of maintenance and breakdowns. FPs are used because of their resistance to very high temperatures, other chemicals, and the increase of under-hood temperatures in vehicles, alongside the need to prevent leaks of fuel and other auxiliary products.

FP applications are a key element of fuel cell technology. A fuel cell is an electrochemical cell that converts the chemical energy of a fuel and an oxidising agent into electricity, yielding higher efficiencies than diesel or gas engines, along with lower emissions and reduced noise. Maintenance of fuel cells is also easier due to its few moving parts. Fuel cells are generally 60% energy efficient, while the typical efficiency of a combustion engine car is 25%. Fuel cells also generate less emissions than combustion engines, with hydrogen fuel cells emitting only water vapor. As such, there are no CO_2 emissions and no air pollutants. FP components are used in over 90% of the fuel cell industry in end products, while accounting on average for ca. 2% of the total weight of the average fuel cell. The electrochemical cell, which converts chemical energy from fed-in fuel and oxidants into electrical energy, dissipates heat in an isothermal process. Using FPs in this component of the final product has increased the performance and energy output of the fuel cells, thanks to their ability to withstand a wide range of temperatures.

FPs also enhance reliability, safety, and communication in aircrafts. They help, alongside other advanced materials, to deliver performance under challenging environmental conditions, providing durable and effective protection against heat and UV aggressive fuels, while facilitating weight reductions. Their flame retardancy enhances safety for travellers and employees. They are used in various critical components such as in seals, hoses, and tubing, as well as in various electronic data and communications equipment. Key examples for this are use of ePTFE for corrosion prevention in commercial airplanes like Airbus 320, or to avoid chafing and friction damage in military helicopters (Apache and Black Hawk).

Recent developments in FP application in aerospace have also enhanced communication, internet access and telecommunications. For example, cable-based antennas developed with FPs and light coaxial cable led to a reduction in hardware capital costs, making them more cost effective for in-flight entertainment.

The benefits derived from the main characteristics of FPs in the transport sector can be summarized as follows:

- Lower fuel / exhaust emissions (both carbon and nitrogen oxides (NOx) gasses).
- Better fuel economy from weight saving.
- Increased lifetime of components.
- Better engine performance.
- Improved reliability and lower maintenance costs.
- Increased comfort (and noise reduction).
- Permits use of alternative fuels (like biodiesel).
- Increased safety (e.g., through reliable performance of parts).

- Higher level of Fire Safety.
- Cleaner environment by avoiding leakage (e.g., oil or coolant leaks).

All the benefits outlined above are in line with the EU Green Deal ambitions (European Commission, 2021a) in relation to environmental emissions from vehicles, and they are deemed critical to ensure safety for the general population in relation to transport.

FPs are used in different automotive components, such as:

- Engine parts:
    - Fuel lines, fuel hoses and turbocharger hoses: turbocharger hoses boost the performance of cars, while increasing the air density entering the engine. Fuel lines and hoses move fuel within the vehicle and are typically made of multi-layered structures containing fluoroelastomers or fluoroplastics. More recently, some fuel hoses have been made of fiberglass braids and PTFE liner bonds which can resist up to 800 °C for different periods, preventing leaks and breakdowns. The range of characteristics make FPs ideal for these applications.
    - O-rings: often made of fluoroelastomers, which are used as seals between two components to prevent leaks. They are widely used in fuel containment systems and fuel injectors.
    - Cylinder head gaskets: an estimated 80% of new engines use multilayers of steel gaskets with a sealant coating made of fluoroelastomers between the cylinder heads and the engine block, with further growth expected. These gaskets seal the cylinders and prevent gas and liquid leakages (e.g., engine oil, coolants).
- Hydraulic and emission control systems:
    - Hoses in hydraulic systems: PTFE is used in inner layer hose constructions in hydraulic systems. These are in contact with petroleum, synthetic or water-based hydraulic fluids and need to resist high pressure. Non-stick properties prevent sedimentation, but bonding with other substances, such as silicone may also be possible. As above, these avoid leaks and breakdowns.
    - ABS break lines: the inner hose of PTFE with loose steel over-braiding allows for better brake efficiency and less aggressive brake pumping when the ABS is activated, due to pressure absorption in the PTFE tube.
    - Shaft seals, valve stem seals: shaft seals are used to seal engine or transmission components. Fluoroelastomers or PTFE are used as a sealing element (lip). These seals are used to protect the transmission system from dust and aggressive lubricants. Valve stem seals (also made of fluoroelastomers) enable adequate

    lubrication of the valve, while being durable and preventing permeability, which also prevents evaporative emissions.

  - Air intake manifold gaskets: air intake manifolds channel air into the engine. The gasket seals the system to ensure performance and minimise leaks. Fluoroelastomers are used as sealant beads for the gaskets. Heat and stress resistance are critical as temperature and pressure are constantly changing in the air injection system. Failure would lead to higher emissions and lower fuel efficiency.
  - Greenhouse emission controls: FPs and fluoroelastomers play an important role in cutting carbon emissions via lambda, NOx or oxygen sensors which contain multiple FP applications, such as wires, form hoses, grommets, and filters, which are all operating in hot engine exhaust gases to optimise engine combustion. They also contribute to nitrous oxide emission reductions with multiple FP components in the SCR/AdBlue (Urea) systems, converting toxic mono-nitrogen gases to alternatives that are safer for the environment.
- Venting products:
  - Automotive venting products: used for lighting, electronic control systems, sensors, motors, powertrains, interior electronics, as well as gas powered, hybrid and electric vehicles. Vents block water, automotive fluids, and contaminants, while effectively reducing condensation. This allows components to vent during rapid temperature/pressure differentials.
- Alternative energy vehicles (FPs are used in battery/fuel cells for electric vehicles):
  - Membrane Electrode Assemblies (MEAs): these are key components in proton exchange membrane fuel cells. MEA facilitate the conversion of hydrogen and oxygen into energy within the fuel stack. These products also feature in stationary applications.
  - Fuel cells and batteries in electric vehicles: FPs are key components for the most novel types of fuel cells and batteries. Examples where FPs are unavoidable are cathode binders, battery gaskets and fuel cell membranes. In these applications, FPs help achieve high voltage and safety of electrolyte systems, required for next-generation batteries.
  - Lithium-ion batteries and electronic systems: FPs provide a host of important characteristics in electronic components, used extensively in automobiles. As an example, no alternative to FPs (PVDF) exists on this specific application due to the unique combination of properties (electrochemical resistance, adhesion/flexibility

  during the whole battery lifetime, and fit with industrial scale manufacturing) that FPs brings compared to other materials.

- Marine sector:
  - Submarines: submarine hulls can be coated with FPs to reduce encrustation, which increases drag and maintenance optimisation.
  - Boats: smoothness and slickness of FP coatings repels dirt and contaminants. Their resistance to corrosion also protects components from salt and mineral damage, reducing maintenance time and costs.
- Aerospace industry: the same characteristics as noted above make FPs suitable for demanding aerospace applications. This includes, but is not limited to, aircraft and spacecraft manufacturing:
  - Insulation for cables and wires in aircraft and spacecraft: wires and cables insulated with FPs show improved signal integrity for critical data transmission. They are particularly important in aircraft interiors, because of their broad temperature and UV resistance, flexibility, durability and chemical resistance to solvents and hydraulic fluids, as well as low smoke generation and flame resistance.
  - Leaky Feeder Antennas: FPs improve in-flight connectivity to wireless networks. They are used (e.g., PTFE) to ensure low smoke generation, flame resistance and durability, and they allow more protocols to run through one antenna, reducing the number of antennas required.
  - Aircraft interior coating: FPs are used for coating due to their flame retardancy, non-fouling, and ease of cleaning properties.
- Agricultural machinery, including but not limited to tractors, combine harvesters, ploughs, harrows, seed drill, planting machines and fertiliser spreader.

2.4.2. Chemicals and power

By enabling efficiency and improving safety, FPs play an important role in supporting economic activity in the chemicals industry in Europe and aiding its global competitiveness. This is particularly important given that the European chemicals sector is a major player worldwide. World chemicals turnover was valued at €3,347bn in 2018. With 16.9%, the EU chemical industry ranks second in total sales (€565bn) out of the different world regions. Germany is the largest producing Member State in the EU with 31.8%, followed by France (13.4%), Italy (9.4%), the

Netherlands (8.7%), Spain (7.4%) and Belgium (6.8%). The UK produced 6.1% from total EU chemicals sales. The chemical industry is the fourth largest producing sector in Europe, and it provides employment to 1.2m people, contributing 12% of the EU manufacturing employment. The chemicals sector leads and accounts for 16% added value from EU manufacturing sectors. The European chemical industry is still a world leader and a highly innovative sector (Cefic, 2020). The chemicals sector is strategically important as it underpins various other sectors in the economy.

FPs also provide health, safety, and environmental benefits. Durable and reliable FP components prevent leaks and facilitate cleaning (via non-stick properties), which reduces the risk of accidents and exposure of the workforce to pollutants and dangerous chemicals. Exposure to such chemicals can cause a wide range of health effects. It is estimated that the willingness to pay to avoid one acute episode of mild dermatitis lasting approximately two weeks, a relatively minor effect, has been estimated as €227. FPs also enable reliable applications that prevent or alleviate pollution, such as filters, membranes, scrubbers, and heat exchangers. Based on a case study of a Polish CHP plant, it is estimated that for this kind of installations alone, heat exchanger technology enabled by FPs could contribute to energy savings worth around €8bn, with CO_2 emission reductions worth around €0.5bn at market prices, or €3bn considering the societal cost of CO_2. While heat exchanger technology is possible without FPs and thus the benefits are not incurred by FPs alone, heat exchangers are significantly less expensive and more durable with FPs when exposed to corrosive flue gases, according to evidence provided during DUs consultation.

Taken together, FPs' characteristics enable outstanding functionality, safety, and innovation in the chemical and power industries, which delivers wider societal benefit, including:

- Increased lifetime of components.
- Lower maintenance costs through corrosion prevention.
- Increased productivity from reduced failures, improved flow of process substances.
- Higher production yields and quality from improved purity of process substances.
- Material cost savings through downsizing and less waste during production and over life-cycle of the product.
- Lower levels of pollutant emission and exposure of workforce to pollutants and chemicals.
- Increased energy efficiency.

FPs are used in different sectors within the chemicals and power industries, such as:

- Chemical and industrial polymerization: FPs support applications involving aggressive chemical fluids. They contribute to corrosion and leaching prevention, lower maintenance, and reduction of emissions. Typical applications include:
    - Lining of piping, flowmeters and fittings, fluid-handling components, process vessels, tanks, storage and transport containers and piping: these materials are frequently made from steel or reinforced plastic lined with FPs (e.g., PFA, FEP, PTFE or PVDF) to prevent corrosion and leakage, due to their non-stick and non-friction properties, and to extend service life. FP linings can be made conductive to prevent static electricity build-up (which causes dust pick up and spark generation) by adding conductive compounds.
    - Filters: PTFE is sometimes used as a filter medium and/or casing to ensure high chemical resistance in filtering particulate from fluids.
    - Sealants: expanded sealants for flange sealing applications are often made of PTFE with a micro-fibrillated internal structure (i.e., a structure characterised by very small fibres) for enhanced stability.
    - PTFE packaging vents: PTFE allows containers for industrial chemicals and cleaners, agricultural products and household chemicals and cleaners to equalise pressure without leaking and rupturing, thereby preventing harm to users and the environment when transported, stored, and opened.
    - Labware products and medicine packaging: FPs are used in sensitive analytical applications in the pharmaceutical sector because of their high purity, temperature and chemical resistance and low surface energy. In medical packaging, for example pills are protected from humidity and to preserve their effectiveness.
    - Non-stick surfaces: FPs help create non-stick surfaces in applications that require temperature resistance. They are used in lined pipes, valves, pumps, tank and reactor linings, gaskets, and seals. They are crucial to the safety of workers and the public, as they keep all kinds of equipment and chemical systems secured. They also benefit businesses by increasing productivity and decreasing the potential for accidents.
    - Polymer Processing Additives: low use levels of polymer polymerization additives (100–1000 ppm) in other extrusion resins can reduce common polymerization issues like dye build-up and melt fracture. This results in better surface quality, less waste, increased productivity, and a smoother extrusion process from start to finish, including a reduction in energy consumption. They also allow for thickness

    reduction in film applications, reduction of clean outs, resulting in longer continuous manufacturing runs.

    - Water filtration: PVDF is used in membranes for seawater pre-filtration, filtration of surface, industrial and waste waters. Membrane formation is a complicated phase separation process where the ultimate pore size, pore connectivity, strength, chemical resistance, and fouling behaviour depend heavily on the choice of material. Vast majority of membrane products used in ultrafiltration, microfiltration and bioreactors used in wastewater treatment are made of PVDF, which exhibits far superior properties in terms of strength and chemical resistance than other options.
    - Fluorinated ion exchange membranes: FPs, more specifically fluorinated ion exchange membranes (IEMs) are used in electrolysers at electrolysis plants to produce fundamental commodity chemicals for the entire European industry such as chlorine, caustic soda, and caustic potash. Fluorinated IEMs provide excellent chemical stability in harsh electrochemical operating conditions of chlor-alkali production.
    - Extrusion and moulding: fluoroelastomers allow stable extrusion and moulding processes for every type of technical rubber part and fitting in a wide range of polymerization constraints, reducing the risk of failures, and increasing productivity.
    - Sensors: Capacitive sensors could not be made without high-purity FPs, and their connecting cables are often shielded with FPs.
- Lubricants and greases: PTFE in the form of micro powder is added into various matrix materials to reduce surface friction and mechanical wear, e.g., in systems where one component is expected to act rubbing against another one. In thermoplastic compounds they reduce or avoid the need for lubrication of the finished components, both injections moulded or extruded. Extrusion rate and quality can be improved, increasing out-put rate, avoiding marking, surface defects, reduced surface contamination and sagging. This also improves scratch and chemical resistance, while minimising water uptake. Typical applications end uses are automotive, aerospace, industrial machinery, and semiconductor industries. This reduction of friction is important for the proper functionality of the numerous industrial equipment parts used in these sectors. In sliding materials, they are used as additives to waxes, inks, paintings, thermoplastics, elastomers, synthetic oils, and greases. They may also be used as additives to fluorinated oils. Some key applications include:

- Thermoplastics: parts made with the addition of micro powders, like gears, benefit from improved wear resistance, reduced friction, and elimination of stick-slip behaviour.
- Elastomers: Standard elastomer polymerization methods can be used to incorporate PTFE micro powders to enhance wear resistance, reduce friction and facilitate mould release.
- Lithographic, flexographic, and gravure inks: micro powders give better image protection and higher productivity, on top of better slip and surface smoothness.
- Greases: PTFE micro powders properties, such as chemical inertness and non-flammability, are key elements for greases to obtain approval to operate in environments where gases and other hazardous products are present.
- Coatings: The main benefits provided by micro powders are abrasion resistance and anti-friction properties, especially important in coatings for industrial applications.
- Paints: the addition of PTFE micro powders helps give paints easier cleanability thanks to improved anti-fouling properties, and present easier and higher spreading rate thanks to the extra lubricity provided.
- Drinking water: PTFE is allowed by ACS, UBA, WRAS, standard 61 as only solid lubricant with thickening properties. PVDF is allowed for drinking water pipes and filtration membranes.
- Oil, gas, and mining industry: FPs and fluoroelastomer products provide excellent high temperature and aggressive fluid resistance in sealing and fluid transport applications. They also combine the most effective stability to all sorts of chemicals and fluids, such as oil, diesel, or ethanol mix. With a low permeation rate, fluoroelastomers enable the meeting of stringent regulations on gas emissions by significantly reducing leakage. Drilling processes and other downhole fluids contain additives likely to degrade standard rubber. FPs provide reliable and durable equipment which improves the safety and affordability of oil and pipe operations. Due to their ability to resist extreme heat and a variety of harsh chemicals, fluoroelastomers improve the reliability and safety of fuel system sealants, O-rings, and field equipment. Furthermore, FPs provide acid resistant properties for crude oil transfer, in turn improving the safety of pipeline operations.
- Rings, valves, and pumps: the use of FPs reduces replacement and downtime of these components, which helps the extraction and handling processes. FPs are

  - well-suited as they can resist a variety of demanding chemical environments and mechanical stresses.
  - Tubes and pipes: FPs used in the lining of down hole tubing for oil extraction provide chemical and corrosion resistance to the oil extraction process. They are well-suited as they resist the demanding chemical and temperature environment of deep well extractions.
- Conventional Energy: due to their heat, oil and chemical resistance, alongside mechanical properties, FPs are widely used in thermal and other power generators, as well as a range of further applications in the power sector: The main applications are:
  - Filters: due to the chemical resistance of PTFE, filters for dedusting of highly corrosive flue gases (e.g., humid sulphur oxides (SOx) gases, hydrogen chloride (HCl), HF) are often made from woven PTFE. This reduces pollution from fossil fuel power plants and waste incineration plants.
  - Flue gas heat exchangers: PTFE or PFA tubes are frequently used in flue gas heat exchangers for heat recovery and heat displacement. They help in corrosion reduction and aid with cleaning.
  - Cables: the heat, oil, and chemical resistance as well as the mechanical properties of FPs mean that they are often used for cables and other equipment, including at power generation plants.
  - Fluid handling, filtration, and gas sampling in the nuclear industry: FPs such as PFA are widely used for tubes and vessels to handle corrosive liquids and provide a low metals background. Gas handling and filter mediums and casings in the nuclear industry are also often made from FPs.
  - Coal fired boilers: used in mercury control systems to reduce emissions from flue gas streams, these simple systems are resistant to fouling, given their non-stick characteristics and that they can last over 10 years, removing up to 2 tonnes of mercury.

2.4.3. Cookware

FPs are specifically approved for food and drug polymerization in the EU by EFSA. This is confirmed through Regulation (EU) No. 10/2011 including all amendments which provide a positive list for monomers and additives. Corresponding FDA approvals exist as well in the US.

Specific migration limits and residual contents are also outlined in the EU Regulation. The positive list is regularly updated based on the latest scientific findings.

FPs are mainly used in pans, pots, and baking trays. PTFE powder coatings have extremely high temperature resistance as well as excellent surface release properties. The low surface energy, stability, and chemical resistance of PTFE provide non-stick properties to prevent food from sticking and burning, facilitate easy cleaning, provide durability and corrosion prevention. This makes them suitable for use in dishwashers, and it also reduces the use of fat/oil in cooking. These products are designed to be used safely at high temperatures (up to +260 °C) above the smoke point of most cooking oils and fats.

FPs offer a number of important benefits in food contact materials. They enable functionality in cookware and bakeware including:

- Increased lifespan of the product to up to 20 years (hence consumer savings from less frequent replacement).
- Non-stick cooking, avoiding marks/burns.
- Easier cleaning, including use in dishwashers.
- Reduction of fat/oil use in cooking.

It is worth mentioning that, in 2017, the Danish Consumer Council THINK Chemistry selected 16 frying pans from the Danish market. These products were tested for the release of unwanted fluorine substances. In the test, the frying pans were first washed. They were then filled with olive oil and put in the oven at 200 degrees for 30 minutes. The olive oil was then tested for the content of 22 specific fluorine substances. It was also tested for so-called total organic fluorine, which is a broad term for fluorine substances. No release of fluorine substances was found in any of the frying pans. However, the test shows that the frying pans tested did not release these substances to food. If frying pan material contains fluorine substances in their non-stick coating, the substances are therefore well-bound in the pan's material (Danish Consumer Council, 2017).

Some respondents to the survey delivered to DUs for preparation of this RMOA, highlighted that losing non-stick effects for cook and bakeware would have indirect effects, such as increases in the amount of burnt food that could be digested by consumers, or the use of increased amounts of fat for cooking, which could eventually lead to health issues that may have an impact in costs for the EU society in terms of sanitary treatments; furthermore, increased amounts in the use of cleaning products (e.g. water, water heating, detergents) could be accounted for as well, with additional environmental and related costs.

2.4.4. Electronics (including semiconductors)

Semiconductors are used in millions of components in power devices, optical sensor and light emitters in industrial operations, consumer electronics and healthcare applications. These include PCs (personal computers, laptops, servers, and tablets), communications (broadband internet, mobile phones, smartphones) and other consumer electronics appliances (television sets, music players, gaming consoles, household appliances and fitness gadgets), as well as various medical devices. Based on information from the European Semiconductor Industry Association, based on the World Semiconductor Trade Statistics (ESIA, 2020), in 2019 Europe accounted for revenues of $0.04bn out of a total of $0.41bn worldwide, which represents 10% of the total market. However, it is to be noted that this percentage is forecasted to drop to 8.2% in 2021. It is relevant to note that all other regions in the world (Americas, Japan, Asia Pacific) are expected to increase their revenue values in this market, with Europe being the only region decreasing (3.2% expected revenue decrease). Indeed, in a recent joint declaration from 19 EU Member States (European Commission, 2020b), the 10% market share figure for Europe in the overall semiconductor market is confirmed, providing a figure of €0.44bn for the global market. This document also refers to the need for Europe to ensure its sovereignty and competitiveness in this sector, due to the increasing dependency on semiconductor products imported from other regions in the world – notably those used for electronic communications, data polymerization and compute tasks, including processors. The signatory Member States express the need for Europe to strengthen its capacity to develop the next generation of processors and semiconductors.

Semiconductors contribute to improved energy efficiency and performance and are present in virtually all modern electronic devices. Ranked as the most R&D intensive sector by the COM, the European semiconductor market supports some 200,000 jobs directly and up to 1,000,000 indirect jobs in related activities in Europe.

FPs enable outstanding functionality in electronic equipment on which we rely every day, delivering wider societal benefit such as:

- Ever improving affordable microchips and Light Emitting Diodes (LEDs) due to higher production yields in semiconductor manufacturing.
- Manufacturing cost savings (component lifespan increases, lower maintenance cost, lower material consumption).
- Reduced environmental risk (leak prevention, lower exposure of workforce to chemicals).
- Improved performance of high-volume data transmission.
- Increased reliability and lifetime of electronics.

- Facilitation of cleaning of electronics.
- Improved reliability of electronic systems that control a majority of safety critical operations in industrial use.
- Improved fire safety.

FPs are critical to the semiconductor manufacturing process. Semiconductor polymerization requirements are highly specific. Here, various FP components can stand up to the aggressive etching chemicals and provide the necessary purity required in the production of microchips and other electronics, where even trace contaminants can severely affect production yield. Semiconductors are extremely intolerant of particulate and chemical contamination, which, even in trace amounts, can cause severe decrease in electricity yields in the ultimate product, with significant implications for their DU. Some specific applications where FPs are relevant in electronics applications are described next:

- Fluid handling components (e.g., tubing, piping, fittings, valves, pumps, vessels, instrumentation): FPs such as PTFE, PFA and PVDF are used as the main material, coating or lining for components handling crucial aggressively reactive and/or high-purity polymerization fluids. This enables greater integration, reduced, or avoided contamination (e.g., ionic contaminants) and very low extractable and leachable levels, providing greater reliability and endurance. These properties are compatible with aggressive chemicals but can also deliver the required purity, making FPs crucial in the manufacture of semiconductors and electronics.
- Wires and cables: The use of FP in wires and cables provide excellent (di)electric properties, higher temperature rating, excellent high and low temperature performance as well as fire and flame retardancy, and superior chemical resistance. These properties result in improved cable lifetime, thinner insulation thus leading to a smaller and lighter final product, and the possibility to provide more current/power for the same size of conductor or using a smaller size product for the same current.
- Printed circuit equipment parts and packaging: semiconductors, microchips, and other electronics components which are manufactured with or contain FP components are used in a very wide range of other applications and sectors. These in turn enable much of the functionality in a host of other products, such as modern cars, lighting, the internet, medical devices, home appliances and televisions. The use of FPs such as PTFE, PFA and ETFE in semiconductor equipment parts provide heat resistance, UV-resistance, and chemical/contamination resistance.
- Alongside other substances and technological developments, FPs have played an important role in achieving the so called “Moore’s law” – a remarkably accurate

prediction made in 1965 that computing power would dramatically increase in power, while decreasing in relative cost. This, in turn, is driven by increases in the number of transistors per square inch in a microchip. As above, this is evident in increased polymerization speeds and greater computing power in physically smaller components.

- Electronics - ‘Internet of things’: Modern semiconductors are not conceivable without the use of FPs. Their chemical resistance is needed in the manufacturing of ever more complex and bigger semiconductors, Micro-electro-Mechanical Systems (MEMS) and chips, alongside excellent data cable insulation for higher polymerization speeds and lower data losses. It is estimated that there are 6.4 billion items connected to the internet. This includes smart television, smartphones, smartwatches, smart kitchen appliances (e.g., fridges, kettles), and more. In the case of home appliances, this is not only to enhance users’ experience, but it is also envisaged to play a key part in the so-called “energy on demand” concept, in which electricity demand is shaped by smart devices at a regional or national level, shaping peaks and reducing energy supply costs. In this sector FPs are used in many of the manufacturing pipes, vessels, valves, pumps and other etching and cleaning components/semiconductor components, in printed circuit boards, release films and coatings, wiring and cabling. They further play a key role thanks their resistance to chemicals, temperature, avoidance of fluid degradation and metallic contamination, enabling the manufacturing of the smart devices mentioned above.
- Electroactive fluorinated Polymers: The high electronegativity of the fluorine atom makes C-F bond very polar. The atomic size of Fluorine atom is close to the one of Hydrogen. It gives the ability of some specific FP to have polymorph crystallization. Combining these two characteristics, high polarity of C-F bong and ability to crystallize in different form, some specific FP exhibit unique electroactive properties. This is, in particular, the case of P(VDF-TrFE) copolymers. These materials are soluble in selected solvent and crystallize directly from solutions in ferroelectric phase. These materials and their derivatives such as P(VDF-TrFE-CTFE) and P(VDF-TrFE-CFE) exhibit then piezoelectric, pyroelectric, high-k or electrocaloric properties. They are the subject of intensive research and developments in the emerging fields of printed and organic electronics. They are the key materials for new generation of sensors, actuators, energy harvesting or solid-state cooling devices. Compared to classic inorganic ferroelectric or piezoelectric material (such as PZT), they do not contain any toxic component such as Lead. They make possible the design of new functional electronic devices, thin, flexible, all organic and recyclable. Targeted applications are for example integrated smart sensors for Structural health monitoring of renewable

energy structures such as windmills, hydrogen tanks and batteries. Integrated in the constituting material, these organic FP based printed and recyclable sensors will increase the lifetime of the structures, increasing their reliability and safe use. Many studies are on-going to take advantages of their piezoelectric properties to develop energy harvesting devices, such as autonomous sensors or electronic devices. These sensors will not need any connection or battery, it will allow cost and material reduction for sensor system and easier recyclability. They are also subject of intensive research in medical applications, to develop smart catheters, including FP based actuators and sensors, battery free pacemakers, or intelligent non-intrusive system to monitor health.

2.4.5. Food and Pharma

FPs are used in different components involved in food, dairy, beverage and pharmaceutical manufacturing and polymerization equipment. FPs enable durable polymerization equipment to ensure high purity of food and pharmaceuticals, even when ultra-pure substances, extreme temperatures and/or aggressive chemicals are required. In pharmaceuticals, high purity is vital for the effectiveness and safety of (often lifesaving) drugs. In food, it ensures safety and avoids contamination. For both sectors, FPs play an important role in production efficiency.

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA, 2020), the total European industry accounted for €0.28bn, with €0.48bn in exports and €0.04bn in R&D investment, while providing direct employment to 795,000 people, with estimated three times more indirect employment. In 2019, Europe accounted for 22.9% of global sales from this sector.

FP coatings and components enable a high level of efficiency by preventing corrosion and facilitating cleaning, thus reducing maintenance, material consumption, etc. Corrosion prevention has a large potential for cost savings in the food and pharmaceutical industries.

Polymer polymerization additives can reduce the surface roughness of oil pipes, water pipes and tubing. In other applications they allow, in combination with resin, selection to downgauge films while maintaining mechanical properties. This results in better surface quality, less waste, increased productivity and longer continuous manufacturing runs and a smoother extrusion process from start to finish. They also allow for thickness reduction in film applications, reduction of clean outs, further resulting in longer continuous manufacturing runs. High performance polymer polymerization aids based on FPs are essential in the manufacturing of new light weight packaging materials and contribute to lower volumes of waste, helping in the processing of new types of polyolefins such as high-molecular weight Metallocene Low Linear Density Polyethylene resins and are intrinsically needed to achieve cost efficient and high-quality manufacturing.

FPs play an important role in food safety and cost-efficiency of food and beverage manufacturing. This sector, in turn, plays an important role in the European economy. As with other sectors, efficiency is important for global competitiveness, keeping costs to consumers low. Avoiding contamination in production is essential. FoodDrinkEurope estimated that the sector accounted for 15.2% of turnover and some 12.2% added value of the manufacturing industry in 2020. Around 291,000 companies were involved, employing some 4.8 million people, and generating turnover of €1.21bn. A large number of companies in the sector are small and medium enterprises (SMEs) – some 290,000 accounting for 99.2% of all companies, 42.7% of turnover and 58.1% of employment. Annual R&D expenditure is around €2.9bn. The food sector is a key contributor to trade balance, accounting for 18.8% share of the EU global exports, with a sales value of almost €120bn (FoodDrinkEurope, 2020).

The food and drink industry needs chemically inert, pure, and high-performance materials that facilitate cleanliness, non-contamination, and easy release in food polymerization components in order to improve the productivity and efficiency. FPs increase the uptime and the throughput.

Key applications of FPs in production of food and pharma products are:

- Lining of valves, piping, tubing, filters, seals, gaskets, and other standard fluid handling components made from or coated with FPs: heat and chemical resistance of FPs provide corrosion protection against aggressive foods, beverages and cleaning products and exhibit a low propensity to impart flavours on other products. Non-stick properties in polymerization equipment ensure efficient polymerization, preserve the purity of the products, and facilitate cleaning.
- Vessels, tanks, and belts: FP coatings are frequently used for vessels to protect the equipment from corrosion, and the build-up of biofilms and other residues, preventing product contamination. FP coatings can be applied to virtually any metal substrate, and belts can be impregnated for anti-stick performance and easy cleaning. Freeze-drying trays use ePTFE membranes because they provide a high vapour transmission rate in combination with highly effective barrier protection.
- Beverage production: among others, FP components or coatings (e.g., aluminium coil coatings for cans) are often used in beer, wine, and other beverage production, to make fruit juices, dairy products, meat and poultry polymerization, soft drink & coffee dispensers, as well as in the polymerization of sauces and condiments.

- Labware products: FPs are used in sensitive analytical applications in food – and especially – pharmaceutical sectors because of their high purity, temperature and chemical resistance and low surface energy.
- Medicine packaging: FPs protect the contents from humidity and preserve their effectiveness, purity, and half-life.
- Ultrafiltration membranes for pharmaceutical R&D: PVDF is used in ultrafiltration membrane for pharmaceutical applications provide high flow rates and throughput, low extractables and broad chemical compatibility.

2.4.6. Textiles and Architecture

FPs provide a combination of waterproofing, breathability, as well as low weight and thinness to clothing and footwear. This increases comfort and performance for professionals and consumers. FPs are used in the following types of textile products:

- Raincoats, jackets, trousers and more: membranes created from FPs (for instance ePTFE (Expanded Polytetrafluoroethylene)) have a microporous semipermeable structure. This provides waterproofing, breathability, and other protective properties to clothes for personal and professional uses, including in particularly demanding environments. Thin, lightweight, durable, and breathable moisture barriers protect against exposure to blood, body fluids, chemicals, electrical discharge, and water.
- Footwear: FP membranes can also be applied to footwear, to manufacture waterproof shoes for consumers and professionals. This also allows feet to transpire, offering protection against chemicals or other liquids.
- Aerospace suits: Astronauts wear suits which contain FP membranes or PTFE coated glass fabric, due to their resistance to low temperatures and to fire, providing durability and electrical insulation properties as well.
- Membranes for composting: Fabric with ePTFE membrane are used as key component for a composting solution for the treatment of organic waste (green waste, food waste, source separated organics, biosolids or Municipal Solid Waste).
- Geomembranes requiring high resistance to chemicals and unique multidirectional strength and long-term outdoor service life suitability.
- ePTFE sewing thread, fibres, and weaving yarn: Used for outdoor applications like awnings, umbrellas, furniture, boat covers, and sails, industrial filtration applications in demanding environments and high-performance ropes.

An example of a technical textile can be provided in a specific intelligent material used by fire fighters. This is formed by two ePTFE membranes providing, in first instance, a highly breathable layer of thermal protection which is positioned directly under the outer material of the garment. The membrane attached to the outer side of this layer prevents liquid penetration from the outside. This thermal insulation layer is combined with a moisture barrier that faces inwards towards the body. This second membrane quickly wicks moisture away and transports it to the outside. It is a lightweight, breathable, and waterproof system that delivers high levels of thermal protection in firefighter gear, while reducing the risk of burn injuries and heat stress in wet and dry conditions.

In relation to architecture and construction, FPs provide durable, fire-safe, easy-to-clean building materials, with mechanical attributes that enable progressive architectural designs that would not be feasible with other materials. PVDF coatings are more durable than conventional coating technology for construction textiles, lasting between 2 and 5 decades; they require fewer re-coatings and do not create VOCs; when using conventional technologies, each re-coating creates VOCs.

The unique combination of properties of FPs makes them a product of choice for many challenging applications in architecture. Many landmark buildings of the last few decades have utilised these properties. Specific coating systems can reduce building cooling costs and the associated energy use by between 4% up to 22%, depending on colour, geographical location, climate conditions, and substrate type. Reducing carbon emissions from the housing sector, including through improved temperature management, is a goal of the European Green Deal (European Commission, 2021a). Architectural design plays an important role as part of the European "creative industry".

The benefits derived from the use of FPs in architecture and building materials include:

- Combination of waterproofing, breathability, and comfort (thin and light).
- Increased lifetime of the product or building component, even in extreme environments.
- Chemical resistance and UV stability.
- Reduced maintenance of building structures.
- Novel architectural designs requiring flexibility and thin materials.
- Weight reduction of building structures.
- Improved fire safety - No flame propagation and low smoke generation.
- Improving energy efficiency of buildings.

- Facilitates composting.
- Non-fouling and easy clean.

Some examples of uses in construction materials are described next:

- “Cool roof” technology: a group of multidisciplinary scientists developed a new type of PVDF emulsion resin that does not require the use of solvents and high bake temperatures. This resin has been used as the base of reflective white roof coatings, which is known as “cool roof” technology. This PVDF resin enables roofs to have a total solar reflectance of above 65%, which is required to obtain an Energy Star® rating. Moreover, these roofs must maintain at least 50% of this reflectance for 3 years after receiving this rating. A typical white paint based on this new resin has an initial total solar reflectance of 81% and maintains 78% up to five years later (3% reduction). As a result, these roofs provide excellent energy efficiency and have a lower life-cycle cost than most traditional coatings.
- Coatings for architectural applications: includes FP-based paints, FP coated glass fabric roofs, and laminated coatings (e.g., aluminium coil coatings), amongst others. They provide resistance to UV radiation, water, oil, dirt, and corrosion and are impermeable to gases, which makes them excellent for outdoor applications, especially on roofs of large infrastructure constructions, such as airports, stadia, and skyscrapers. When used in paints, they maintain paint properties (notably colour and shine). They prevent mould and moss growth and are fire resistant, an essential property for the safety of the thousands of people who gather inside these buildings. There is also evidence that specific coating systems can reduce building cooling costs (between around 4% up to 22%, depending on colour, geographical location, climate conditions, and substrate type).
- Bridge and offshore bearing pads: these are made from PTFE as it has the lowest friction coefficient of all plastics. Fluorourethane coatings have an effective life exceeding 50 years and can reduce life-cycle costs for coatings on steel and concrete bridges.
- Architectural films: films made from FPs such as ETFE are used as parts of the roofs in stadia, domes, and other structures. They can be made translucent, allowing some natural light through but keeping out heat, improving energy efficiency for such buildings. The excellent insulating properties allow for less material to be used, reducing the weight of the structures. They are usually shaped as panels or cushions and may be accompanied by a LED-light system enabling external colour and colour changes. Since the construction of Allianz Arena in 2005 and Beijing National Aquatics Centre in 2008, many other new-build stadia have included FP cushions and films. FPs

enable a much lighter and versatile design with possibilities of enhancing the public experience.

- Buildings that are protected by PVDF coatings require zero recoating (each recoat emits VOC), thereby ensuring extra-long service life. The durability of PVDF coatings means that they extend the useful service life of the underlying substrate, thereby greatly lowering maintenance requirements that would result in downtime for the building. Furthermore, PVDF coatings are used in super-durable cool roof systems, whose long-life solar reflectivity is well documented in terms of long-term energy usage minimization and infrequent recoating steps.
- Films for greenhouses: ultra-thin ETFE films (ETFE foil) are used to substitute traditional glass roofs in greenhouses. They are treated with an anti-drip coating, designed to increase the yields of plants, flowers, fruits and vegetables grown inside commercial greenhouses. ETFE foils allows maximum UV light transmission to ensure early blooms and higher quality fruit and vegetables. The film’s durable chemical composition is self-cleaning, providing the following advantages:
    - Excellent light transmission up to 94%.
    - Anti-adhesion/Easy cleaning.
    - Improvement of crop quality by UV light transmission (‘UV cut’ grade also available).
    - Excellent durability due to minimal effect of ageing on tensile strength – a service life of over 30 years.
    - Improved hail resistance compared to glass.
    - Less structural elements (steel) are required thanks to the lightweight properties of the film, hence more sun can enter the greenhouse.
    - Stable at high and low temperatures (-100 °C to 200 °C).
    - A double layered roof saves over 30% energy compared to a single layer glass roof.
    - No breaking/splintering, high resistivity against tear propagation.
    - Anti-dripping characteristics prevents condensation droplets from dripping down.
    - Non-flammable material certified B1 in DIN4202 part 1.
    - Improved light transmission at all angles of incidence, compared to other covering materials.

2.4.7. Medical applications

To ensure patient safety, medical devices need to be made of very high-quality materials. FPs provide an effective solution to the most challenging medical device demands. The below information is an example of the importance of FPs to medical applications. Thanks to their unique combination of properties, FPs are the material of choice, exhibiting excellent performance in a wide range of medical applications. FPs enable outstanding functionality and safety in health care, which delivers wider societal benefit, including:

- Reduced risk of cross-infections and thus medical complications.
- Increased lifetime of implants reducing risk of failure and risk of replacement.
- Improvement of tissue attachment and cell adhesion without an adverse reaction.
- Higher consistency of dosages, increasing effectiveness and safety of drugs.
- Less frequent clogging and thus less frequent re-application/replacement for the patient (e.g., catheters, tubes).
- Improved functionality of medical equipment (e.g., filtering and venting).
- Enhanced non-invasive surgical procedures with guidewires, reducing risk of complications.
- Enhanced miniaturisation for keyhole surgery.
- Material characteristics ideal for minimally invasive procedures, such as endovascular repair.

FPs enable excellent performance and long lifetimes in medical equipment, such as surgically implantable medical devices, catheters, guide wires, filters, and pumps. This reduces the risks of failure, replacements, cross-infections and clogging of medical equipment, contributing to the reduction or avoidance of medical complications and the associated pain and public cost.

It is relevant to underline that in the course of the COVID-19 pandemic that the world is facing at the time of preparation of this RMOA, a significant number of medical equipment that is being used to deal with the medical treatment of patients relies on the availability of FPs, including face masks, ventilators, gaskets, testing kits, emergency 3D printing solutions to generate additional PPEs on time.

In the medical sector, FPs are used for example in:

- Surgically implantable medical devices such as vascular grafts: Often made with expanded PTFE, grafts are critical in current surgery technology to replace damaged vessels in various body parts. Minimally invasive medical devices, with examples including Stent Grafts or Septal Occluders, are often used for life-saving operations such as repair of aortic aneurisms or holes in the cardiac septum. Guide wires lined with PTFE facilitate surgical procedures, helping to shorten their duration, reducing patient risk, and facilitating complicated procedures. Other implantable devices include for instance surgical meshes for hernia repair and sutures for use in vascular, cardiac, and general surgery procedures. The durability and biocompatibility of implants made with FPs reduces the risk or frequency of the implant having to be replaced.

- Medical imaging and analysis (via electronic chips and semiconductors in X-ray, MRI scan, CT scan, and echography), as well as medical analysis (blood, tissue, urine analysis).
- Heart patches: FPs are used in patches used for cardiac reconstructions or repair, where it is important that complications associated with the formation of tissue attachment to the material be minimised to facilitate reoperation. Heart patches made with FPs usually have different layers; external layers made of expanded PTFE and a middle layer made of an elastomeric FP. PVDF flat sheet filtration membranes exhibit extremely fine porosity for highly selective filtrations of medical serums and solutions and body fluids. The high purity and durability of PVDF makes it safer for human healthcare applications where highly selective size exclusion filtration is required.
- Additional medical equipment: pumps, compressors, portable oxygen concentrators, analytical equipment (HPLC, UPLC), bearings for surgical tools (e.g., drills), connectors, sealings, adaptors, housings, lids. FPs provide numerous properties such as lowering friction, reduced wear and controlling of leakage of media with bearings and seals, as well as safety devices for the handling of medical needles.

2.4.8. Renewable energies

Alongside increasing operational lifetimes, FPs have decreased maintenance costs and increased energy generation potential. FPs have contributed to the technical advances that have enabled growth in wind and solar PV energy generation, as well as the development of lithium-ion batteries.

The average cost of PV cells has dropped significantly over the past years, driven by increases in technological efficiency. FPs provide optical transparency and electrical insulation to PV panels, as well as protecting them from wind, humidity, UV, extreme temperatures, and chemicals. This increases the efficiency and lifetime, minimising failures, maintenance stoppages and associated costs. Failure rates are as low as 0.1% in recent designs using FP film-based back sheets, compared to 45% in early designs. FPs in PV front sheets and back sheets are lightweight and allow for more efficient panel production, reducing production and distribution costs and making installation easier.

Wind energy manufacturers seek to reduce energy costs and reduce blade manufacturing cycles by producing wind blade structures more efficiently. FP based release films enable efficiency gains in wind turbine production. PTFE mould linings for wind turbine blades increase the number of blade cycles before replacement 10-fold. FPs also facilitate advanced energy storage and conversion technologies, such as lithium-ion batteries. Greater use of these technologies is important to meet growing energy demand, whilst also reducing carbon emissions. Uses of these batteries are growing rapidly, expected at a compound annual growth rate of some 11% from 2018 to 2025. While initial growth was driven by consumer electronics, and their use in mobile phones, tablets, and power tools, demand increases are expected from electric vehicles. As above, to increase uptake, cost-effectiveness needs to be increased, with decreasing costs alongside improved battery performance. Biaxially oriented PVDF film has unique properties (e.g., abrasion and corrosion resistance), and its potential for use in bilayer films is expected to support the further development of lithium-ion battery technology.

FPs enable outstanding functionality in renewable energy, supporting their development and delivering wider societal benefit, including:

- Increased lifetime of components.
- Lower maintenance costs.
- Increased efficiency from improved functionality and reduced failures.
- Increased efficiency in the manufacturing process.
- Indirectly: Enabling sustainable energy and facilitating remote location of installations.
- Design flexibility.
- Corrosion prevention.
- Pollution abatement.

Some specific uses of FPs in the renewable energy sector are described next in more detail:

- Photovoltaics: fluoroplastics films are suitable for use in a wide variety of applications, including PV cell glazing. The films can be adapted to conventional processes and secondary operations such as heat sealing, thermoforming, welding, heat-bonding, lamination, and dye-stamping. Each of the film grades is available in various sizes, weights, and thicknesses, meeting even the most specific requirements.

  - Front sheets: frequently protected by FPs (e.g., ETFE, FEP and PVDF film), providing weather resistance (heat, water, abrasion, chemical), optical transparency (stable and high light transmittance), low surface energy (non-adhesiveness, easy clean), high barrier performance to oxygen, excellent fire resistance, flexibility, and cost-effectiveness.
  - Back sheets: FPs (e.g., ETFE and PVDF) are widely used to improve their primary function, such as electrical insulation and protection from humidity and sunlight. The FPs used are resistant to sunlight degradation and are resistant to most chemicals (including environmental pollutants) and heat, while preventing the permeation of gases and liquids. They exhibit high dielectric strength and volume resistivity, as well as low flammability.
- Solar applications:
  - Vents: FP-based vents are used in solar applications like junction boxes, concentrating PV modules, inverters. They monitor for rapid pressure equalisation, contamination protection and condensation reduction.
- Wind turbines:
  - Paints and coatings on the main towers and blades of wind power generators: FPs (e.g., PTFE and PVDF) provide high weather resistance. Their use contributes to increased service life and reliable operation in harsh environments, the extension of maintenance cycles and they also contribute to friction reduction; specific products based on FPs have been developed to reduce ice build-up on turbine blades.
  - Release film: FPs-based (e.g., PVF and ETFE) release films support the production of wind turbine blades.
- Lithium-ion batteries: FPs (e.g., VDF/TFE copolymer, PVDF, VT) are used as electrode (cathode) binders for active materials in lithium-ion batteries. They are used for their chemical resistance and endurance, ease of polymerization, adhesion, and voltage stability. PVDF can provide superior flexibility, allowing for high electrode densities and higher power densities. Also, PVDF is used in separator coatings, for which this material is absolutely key to ensure a safe usage of the battery during its whole lifetime.
- Polymer electrolyte membrane/proton exchange membrane (PEM) fuel cells: various FPs are used in several components, including the gas diffusion layer (PTFE, FEP), the

separator (ETFE, coatings) and drainage piping (PFA). Useful FP properties include protonic and electrical conductivity, permeability, as well as resistance to oxidation, chemicals, and heat.

- Hydrogen technology: Hydrogen produced through water electrolysis is one of the green hydrogen production options. Using ion exchange membranes based on fluoropolymers (ionomers) in water electrolysers offers an environmentally safe way to generate large amounts of hydrogen without emitting CO_2. Fuel cells convert hydrogen to electricity which is crucial to reach the stated target.

Selected examples of FP enabled innovations:

- Energy Flexible electric generators: Polyvinylidene fluoride (PVDF) is a versatile material, with properties that allow it to generate charges when subject to mechanical stress (piezoelectric). Recent research has made it possible to use this material to create wearable piezoelectric generators (PEGs), these are mechanisms that can harvest mechanical energy from human movement and convert it into electricity. For instance, PVDF PEGs have been embedded in shoes, allowing the wearer to generate a power and voltage up to 20 mW and 60 V, respectively. Another application is in backpack straps. Here, the mechanical strain of walking with a backpack can be converted into electricity by placing PVDF into the straps. Other kinds of PVDF PEGs are used to harvest mechanical energy from urban and natural environments, such as road deformation under vehicles passing, vibration and water flow. It is hoped that this technology may be capable of powering streetlamps and nearby buildings, as well as sensors for monitoring traffic density and the condition of the road.
- Air Filtration for Gas Turbines: filters are susceptible to high pressure drop spikes as they reach the end of their service lifetime. This is due to swelling of particles in wet or humid conditions. High efficiency particulate air (HEPA) filters are highly efficient and capture virtually all particles in an airstream over their lifetime. When the filters start approaching their end of life, trend monitoring begins to show sensitivity to wet and humid conditions. The hydrophobic HEPA filters, a synthetic composite with ePTFE membrane, delays this effect, allowing for a longer lifespan, even in harsh conditions.

2.4.9. Consumer articles

Even if the main field of application of FPs is in industrial uses, it is the case that due to their wide variety of properties these products can be present in many household and consumer appliances.

FPs enable outstanding functionality, safety and innovation in many products used by consumers, including:

- Increased lifetime of the product (leading to consumer savings from less frequent replacement).
- Non-stick cooking, avoiding marks/burns.
- Easier cleaning, including use in dishwasher.
- Reduction of fat/oil use in cooking.
- Combination of waterproofing, breathability, and comfort (thin and light).
- Waterproof properties.
- Fireproof properties.
- Chemical resistance.

It is to be noted that consumers may interact with devices that have been discussed in previous sections (transport systems, semiconductors, textiles, or cookware). The following few examples of additional FP uses fall under a wider definition of "consumer uses" and intend to illustrate the variety of additional uses. While the list is by far non-exhaustive, it gives an idea of how numerous and varied these uses can be:

- PTFE packaging vents: these vents allow containers for industrial chemicals and cleaners, agricultural products and household chemicals and cleaners to equalise pressure without leaking and rupturing, thereby preventing harm to both users and the environment.
- Wood Decks: to limit maintenance and provide longer life to outdoor surfaces such as wood decks, FP -based stain release agents are applied to wood furniture inside and outside of a house and can improve product lifetime.
- Solar Cells: as of today, solar cells and panels have become a consumer product in the drive to reduce energy consumption at home. To manufacturers of solar cells and panels, FP resin grades provide weather resistance, which are used for surface protection. They contribute to efficient PV power generation by extending the lifespan of solar cells and reducing power generation cost.
- Faucets: Applying FP coatings over faucets can substantially improve its anti-smudge properties and add water repellence. Therefore, such faucets are always clean from water stains and fingerprints, for a more premium appearance. Furthermore, thanks to their chemical resistance, the faucets stay cleaner for longer, reducing the need to

clean the faucet with household cleaning products, saving water. Coatings are available to construction professionals, not end customers.

- External Walls: FP-based solutions protect walls exposed to sunlight, wind, and rain, limiting the need for maintenance three times less than when compared to standard paint. Formulated with a hydrophilic agent, the film also becomes resistant to stains and soils. These FP solutions are not directly available to the end customer but only to service providers in the housing industry.
- HEPA filters: as previously discussed, ePTFE membranes are key components of HEPA filters. These filters have become increasingly important for society as they provide an efficient system for indoor air filtering. This has proven particularly useful to prevent transmission of the COVID-19 in houses, offices, and closed rooms, as the use of air cleaning equipment using these filters has increased dramatically during the pandemic that Europe and the whole world continue to face.

2.4.10. Summary from the evaluation of socio-economic information

As an overview of the information provided in this chapter, it appears evident that FPs provide a wide array of properties and benefits to many applications, bringing a high societal value to the EU. Such value goes beyond the contribution of direct manufacturing of FPs in terms of revenue, volume, and employment which, while not negligible, appears to be small if compared with the contribution of FPs along the supply chain. While direct contribution from FPs to those sectors has not been quantified in detail, the qualitative descriptions provided together with the generic information outlined for certain key sectors in terms of overall contribution to the EU economy give a good understanding of the importance of FPs in today’s society.

In short, the key properties of FPs can be summarized as follows:

- Durable, stable, and mechanically strong in harsh conditions in a variety of sectors including but not limited to aerospace, environmental controls, energy production and storage, and electronics, as well as in technical apparel.
- Stable in air, water, sunlight, chemicals, and microbes.
- Chemically inert meeting the requirements for low levels of contaminants and particulates in manufacturing environments essential for the food and beverage, pharmaceutical, medical, and semiconductor industries.
- Biocompatible.
- Non-wetting, non-stick, and highly resistant to temperature, fire, and weather.

While the main uses of FPs are found in industrial sectors, products containing or made with FPs will eventually reach consumers, as these polymers are part of many articles that are used in daily life. FPs contribute significantly to the improvement of life quality in modern society, enhancing development of new technologies and providing numerous benefits to consumers. However, the most remarkable advantages derived from the use of FPs can be linked to additional long-term improvements in key areas considered critical for the development of the EU, which are related to health and safety of the EU population, the development of clean energy technologies that must render the EU less dependent on fossil fuels, the contribution to ensuring that the EU does not fall behind other regions in the transition to a digital economy, and the plan to achieve no net emissions of greenhouse gases by 2050 via the so-called Green Deal (European Commission, 2021a). Some examples of such advantages, as described previously in this section, are:

- FPs are key elements for the decarbonization and climate change objectives of the EU, for example in development of alternative energy elements (fuel cell technology, lithium-ion batteries, MEAs). FPs are also critical components of PV cells in renewable energies, including clean hydrogen. In addition, FPs contribute to control and limit pollutant chemicals carbon and NOx emissions from vehicles by optimizing engine combustion; similar benefits are related to the production of resistant filters for the chemicals industry reducing pollution from fossil fuel power plants or waste incineration plants, or to innovative techniques such as the coal-fired boilers mercury removal system from flue gas systems. Finally, no alternative to the use of FPs exists for the production of lithium-ion batteries and they are used as electrodes binders and separator coatings.
- Use of FPs in the chemical industry prevent leaks from basic components and allows the extension of their service life and provide non-stick properties to equipment, thus keeping chemical systems secured i.e., by avoiding clogging and failure. This contributes to improving health and safety issues, i.e., by reducing risk of failure.
- FPs protect safety of people by improving reliability of critical components in the aircraft/aerospace industry.
- FPs provide critical safety solutions in textile applications, such as improved coats for firefighters or aerospace suits.
- FPs are critical and best material of choice for production of ultrafiltration membranes which are key for obtaining clean drinking water.
- FPs improve organic waste treatments via fabric membranes used for composting.

- FPs enable lower maintenance requirements (and therefore longer life-cycles, reducing efforts to replace and dispose of materials) and higher energy efficiency when used in architecture and construction.
- FPs are critical to facilitating the next generation of technology, contributing to the digital transformation in the EU. FPs are key in enabling production of semiconductors that are used in all sorts of technological devices, facilitating increased speed and reduced size of such devices. In this regard, it is relevant to highlight that a group of Member States have recently published a joint declaration, entitled "A European Initiative on Processors and semiconductor technologies", related to the need for Europe to become self-dependent on the production of semiconductors in order to ensure that the region continues to be competitive, which includes improving the capacity to develop the next generation of processors and semiconductors.
- FPs have applications in medical implants that are critical to help to save lives and improve patient conditions.
- The use of ePTFE membranes in HEPA filters, in the course of the COVID-19 pandemic provides another example of how critical certain uses of FPs can be, some of which could remain unnoticed by society until they become necessary.

2.5. Alternatives

As described in the previous section, FPs offer a wide variety of key attributes that make them highly valuable for many industrial and consumer uses. Overall, while some alternatives might have a similar performance to FPs for a single parameter or property, it is the unique combination of properties required for the applications that sets FPs apart from the alternatives. FPs are an expensive class of polymers and usually selected as a last option when all other non-fluorinated polymers have been assessed and deemed to be inadequate for specific applications. If less expensive non-fluorinated alternatives were available, DUs would have already switched to those for cost reasons. FPs provide the combinations or ranges of properties required for the applications that sets them apart from alternative products. Alternative materials usually exhibit lower performance, increased weight, reduced durability, which would lead to negative effects such as equipment failure, high release of pollutants to the environment, or even higher risk of exposure of working staff to hazardous chemicals.

For each of the key sectors and applications identified, different possible alternatives to FPs were considered in the 2017 SEA commissioned by the FPG (PlasticsEurope, 2017). This information has been reviewed and updated in the course of the consultation conducted to the DUs and FPG members for the preparation of this RMOA. In considering the implications of alternatives, the criteria considered are as follows:

- Technical feasibility: could the alternative provide an equivalent technical function to FPs in the application concerned? Would the alternative provide the final products with the same/similar technical functionality?
- Economic feasibility: would adoption of the alterative incur additional costs to manufacturers, DUs or consumers? This may arise from higher unit costs, process or production changes requiring new or altered machinery or loss of functionality to the end user, which might impose additional costs. Sensitive applications might require expensive and lengthy re-approval processes.
- Availability: is the alternative likely to be available? Is it likely to be available in the required quantities and without undue delay?
- Hazards and risks of the alternative: would the overall risks to human health and the environment from the use of the alternative increase or decrease?

The information on alternatives is based on general feedback on alternatives and on specific examples provided by the supply chain of FPs. As a result, it does not necessarily cover all applications and/or all products. The alternatives mentioned as part of the consultation include steel and other metals; high nickel alloys, polypropylene, Polyvinyl chloride (PVC), glass, ceramics, mica, polyether sulfone, polyimide, ethylene propylene diene monomer (M-class) rubber (known as EPDM rubber), nitrile rubber (NBR), hydrogenated nitrile rubber (HNBR), acrylic rubber (ACM), Ethylene-acrylic rubber (AEM rubber), fluorosilicone (FVMQ, graphite, aramid, slip agents. Each would only be a possible alternative for some of the applications of FPs.

In sectors such as chemical & power, pharmaceuticals or transport, FPs provide resistance to a wide range of low and high temperatures and universal chemical resistance. This “universal” resistance to chemicals is a crucial characteristic of FPs that is not present in any of the alternatives, according to consultation feedback. There are alternatives that are more or less resistant to specific chemicals, but there is not one that is universally suitable.

A high-level analysis of alternatives has been carried out for all of the above sectors. In summary, whilst the implications of substituting FPs differ across specific applications, they include:

- Technical implications include lower performance, increased weight (with associated effects on fuel consumption and fuel efficiency), and reduced durability and reliability. This results in increased challenges (less compatibility and versatility) associated with component design/redesign and operating condition requirements.
- Economic implications include regression of advanced technologies and the reduced ability of Europe to compete and attract high and medium technology manufacturing

investment (if it is not possible to prototype and produce competitive products), efficiency losses, higher initial (investment) costs and higher maintenance costs. The diversity of specific applications would pose major product qualification issues alongside design implications for many sectors of use. Approvals for reformulations of products in certain sectors (e.g., car and aviation industry) may require at least ten years with significant technical and administrative actions required (shorter for direct replacements – longer in cases that require full system re-designs.)

- Environmental / health implications include the potential for higher risk of exposure of staff to hazardous substances, higher safety risks (due to potential vehicle or aircraft failure) and increases in emissions arising from technical regression; some examples in the transport sector include inferior car emission sensors, inferior internal seals, increased fugitive emissions and weight increases. This could put at risk Europe's ability to meets its climate and energy goals following the EU Green Deal (European Commission, 2021a), as well as other key objectives related to the Chemicals Strategy for Sustainability (European Commission, 2021b).

Looking at the replies obtained from the survey conducted on DUs of FPs, out of 42 analysed only in one case is there an indication that alternatives would probably be available, although resulting in certain decrease in performance, which in that particular case may be accepted further down the supply chain. This is a minor and very specific use of FPs in manufacture of leather products, where the FPs are used to provide anti-soiling properties. Silicon based products could be used as alternative with similar results, with the exception of resistance to coffee. So, where this downsize is acceptable for the DUs, the replacement could be considered as viable.

In all other cases analysed, 16 replies from the DUs stated that alternatives are not available that would meet the technical conditions required for the specific application and which render the specific FPs of interest unique. There were 3 replies that claimed not having tested for alternatives, and as many as 12 respondents did not provide any information on alternatives, however it is worth noting that all those respondents rated the use of the FPs as 'important' or 'extremely important'.

Table 40 provides an overview of the different alternatives that have been identified following different consultations with industry, related to the key sector of use and specific applications. These are grouped per market sector, describing the technical, economic, and environmental implications that would be expected.

Table 40. Overview of alternatives

Key market	Sector	Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Chemical & Power	Chemical industry	Stainless steel, copper	Pipes, liners, tubing	FPs are commonly used as liners in stainless steel pipes and valves. Stainless steel is not corrosion resistant as a replacement for these applications. Possible for certain very specific components. However, metals are likely to result in: Increased weight and size/design of components. Inferior resistance to corrosion and/or abrasion. Inferior non-stick and non-friction properties. Lack of flexibility. Rapid corrosion and abrasion (on metal dynamic applications) would be the consequence. Costly redesigns, higher maintenance costs, higher design costs. Higher safety and environmental risks.
		High-performance nickel alloys	Pipes, desulphurisation heat exchangers and filters	Various grades are available for specific applications. They are often quoted as highly resistant to corrosion. FPs are generally more resistant to chemicals and at higher temperatures. Likely to be more costly, especially nickel-chromium-molybdenum alloys. This "universal" resistance to chemicals is a crucial characteristic of FPs that is not present in any of the alternatives. There are alternatives that are more or less resistant to specific chemicals but there is not one that is universally suitable. If there were no FPs, not only would the alternatives have inferior performance: a specific alternative would have to be developed for each manufacturing process, with potential differences across the industry. Only titanium and tantalum could have similar resistance, but their cost is very high, and they do not have other of the required properties. Therefore, they are not considered as alternatives by industry.
		Polypropylene and PVC	Commonly used in pipes and liners	Low resistance to chemical attack and temperature hence lower corrosion prevention. Unsuitable for demanding applications, unless coated or reinforced (for instance with FPs).
		Glass and ceramics	Historically used in several applications	Brittle, considerably heavier and more difficult to transport. Lack of chemical resistance to strong bases and HF.
		Polyether sulfone and Polyimide	Seals	Their thermal resistance is similar to that of some FPs. It is understood that chemical resistance may be inferior. They are also rigid, posing design difficulties.

Key market	Sector	Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Chemical & Power	Chemical industry	Rubbers and silicones such as NBR, HNBR, ACM, AEM rubber or FVMQ	Seals, O-rings, and other applications	Suitable for other applications and resistant to specific chemicals. They have generally lower resistance to temperature changes, abrasion and chemicals compared to FPs
		Graphite and aramid	Gaskets	Aramid is sensitive to acids (i.e., they cannot prevent corrosion) and ultraviolet light. Graphite, whilst chemically resistant, is brittle.
		Zinc stearate, calcium stearate	Polymer Polymerization Additives	While the stearates can be used as processing additives in polymers, their effect is limited both on melt fracture elimination and pressure reduction. high loadings are required which in turn impacts other film properties, rendering the alternatives not acceptable in the packaging sector
		Polysulfone (PSF) and polyethersulfone (PES)	Water filtration membranes	These materials can be used in certain applications, but they are less resistant to chemicals resulting in shorter membrane life. They are too stiff to be used as submersible membranes in bioreactors, where they are clearly not an alternative.
		Boron nitride and other inorganic solids	Lubricants	Reduced chemical stability (e.g., hydrolysis), downgraded lubricity, expensive
	Power	Mica	Insulation material for sensors, probe, and cables	Rigid and brittle, lower chemical resistance than FPs. Performance could be improved with additional insulation (additional weight, similar brittleness).
		EPDM rubber reinforced with lead	Underground cables and submersible pumps	Higher weight, lower chemical and temperature resistance compared to FPs. Due to their inaccessibility, durability is essential, implying increased downtime and higher maintenance costs.
		Slip agents	Cable applications	These are additives designed to reduce friction and provide appropriate lubrication during polymers processing (e.g., adhering a film to a metallic surface). Whilst these perform well for the elimination of melt fractures, die build-up and higher energy consumption may be problematic in some applications.
Food and pharma	Food industry	Ceramics	Coating applications	Commercially available, but the durability of FPs is understood to be superior (see “cookware”).

Key market	**Sector**	**Alternative/s**	**Example potential application**	**Overview of likely technical economic and environmental implications**
Food and pharma	Food industry	Animal or vegetable fats	Coating applications	The use of animal fat-based products would need the use of harsh cleaning methods with powerful solvents, to which staff would be exposed. Higher risk of exposure to carcinogenic degradation products of overheated fats.
		Steel	Processing equipment such as pipes	Steel is already in use. It tends to be coated (often with FPs) to prevent iron contamination / corrosion.
	Pharma	Polymethyl pentene (PMP or TPX)	Labware	It can withstand temperatures of up to 150 °C and can be autoclaved. However, extremely brittle and can break easily at room temperature or if it falls from the table/lab benchtop. Also, FPs have a wider temperature range.
Electronics	Electronics	Polyolefin with flame retardant	Cable insulation	It is understood these do not offer the same resistance to temperature range as FPs (maximum limits differ, but minimum working temperature of polyolefins is higher than that of FPs, reducing their performance in cases where coolants are used to decrease the temperature of data processing systems). Polyolefins also have inferior fire resistance often requiring a flame retardant. Flame retardants commonly increase dielectric constant and dielectric loss which reduce data communication rates. The use of polyolefins would likely result in weaker data processing and slower signal return, reflecting inferior purity, friction properties and stability compared to FPs. If an alternative is found at some point, the industry states it may require at least 10 years to replace equipment and adapt manufacturing methods and processes
		Non-conductive plastics	Historically used in semiconductor manufacture	Unviable. The modern semiconductor industry has stringent requirements and FPs are the only material that can currently protect the processing equipment in which semiconductor are etched and cleaned from the chemicals used in the manufacturing process while at the same time offering the highest purity. Microprocessors and chips need to be increasingly small, yet powerful, preventing metallic contamination and corrosion in order to maximise chip yields.

Key market	Sector	Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Transport	Automotive	Stainless steel, aluminium, or copper	Low permeation fuel lines Protection for plastic fuel lines	Fuel lines made entirely of metal are available in the market for antique cars that do not have to meet modern standards. All metal fuel lines are prone to leakage during crash tests and leaking gasoline or diesel is an immediate fire risk at any crash site. Other polymeric alternatives have difficulties to meet fuel permeation standards and especially with the variety of alcohol containing fuels used today.
		XLPE (cross-linked polyethylene), thermoplastic elastomers (TPE)	Hoses, cables, and wire solutions	Successful for applications in other sectors and in some automotive applications e.g., in cold air intake systems or control elements in car interiors. Although thermal resistance of XLPE and TPE is in the range of that for certain FPs such as standard ETFE, their chemical resistance does not reach the standards provided by FPs.
		Silicone rubbers	Gaskets, cables, or hoses	Silicone materials offer a range of properties that are suitable for other applications used in various applications in modern vehicles such as paint additives, air bag coatings, and radiator seals. Whilst they offer a range of properties suitable for these applications, they do not have the specific combination of properties required in FP applications.
		Mica-insulation (as above)	Mica-insulated sensor cables for oxygen and nitrogen sensors	This is a very specific application with particular requirements. It is likely that sensors would have to be placed in less demanding locations, since these cables are not able to resist the conditions at the optimum measurement point. This would result in less accurate measurements, which would in turn lead to higher emission levels and less efficient fuel consumption, as an accurate control of the air-fuel ratio is essential for fuel efficiency. Also, mica-insulated cables are heavier and more rigid and brittle.
		Polyetheretherketone (PEEK), polyether sulfone	Fuel hoses, lines, gaskets, seals, cables, wire insulation	They have similar temperature resistance. For example, PEEK is able to resist up to 260 °C. They are rigid, which may impact on design possibilities, and chemical resistance is lower. Also, electrical and data transmission properties are inferior.

Key market	Sector	Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Transport	Aerospace	Same as proposed for the automotive industry	As in the automotive industry	Applications in aerospace are even more demanding than automotive: Performance, durability and fire resistance needs are higher. There is no easy maintenance stop when in mid-air. The temperatures near aircraft turbines are significantly higher than most cars. Development cycles are very long in aerospace which would also include the search for alternatives.
Renewable energy	-	Glass (Top sheets) UV-resistant PET or polyimide (Back sheets)	Top sheets / Back sheets in solar panels	Glass has been historically used and UV-resistant PET and polyimide are currently available in the market. Glass is brittle and fragile. As for UV-resistant PET and polyimide, evidence suggests that FP-based back sheets perform better in certain parameters such as adhesion between layers (especially those based on ECTFE).
Cookware	-	Ceramics	Coating for non-stick cookware	Ceramics is already in the market. Initial non-stick properties are acceptable but not as good as those of PTFE-coated cookware. Ceramic-coated cookware is more expensive for consumers since it reportedly loses its non-stick properties considerably faster and has to be replaced more often. For industrial kitchen that use robots, pneumatic transportation processes FP coatings are critical, and alternatives are not readily available.
Medical applications	-	PEEK	Tubes, catheters, and other hospital material	PEEK catheters are commercially available. PEEK is a stiffer material than PTFE or Fluorothermoplastics. PEEK is an alternative for specialty catheter applications. It is biocompatible but it is generally not suitable for uses where longer term (30+ day) contact with tissue or blood is required. As a result, they are inferior to FPs for solutions such as heart patches. Some publicly available evidence suggests that PEEK may eventually be suitable for long-term solutions but is currently comparatively expensive. The sector has particularly strict quality testing and approval procedures, which would delay the appearance of alternatives in the market for the applications where FPs are used.
	-	Polyurethane	Tubes and catheters	It is not suitable for steam sterilisation. Higher costs than current solutions. Concerns with clogging are highlighted by users.

Key market	Sector	Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Textiles and architecture	Architecture	Steel or glass	Insulation materials, pipes, and tubes	They are heavier and more inflexible than FPs. Steel is not resistant to corrosion, leading to higher maintenance costs. Glass is more fragile to hail or other impact. They are not able to meet the design requirements of FPs.
		Polycarbonate sheets	Membranes for architectural applications such as roofing	They are resistant to temperature and can withstand force. Polycarbonates have a tendency to yellow in external applications in contrast to Fluoropolymers. PVC/PES membranes for architectural applications are common. However, these are often coated with a protective layer (often made of PVDF, a FP) providing UV-resistance and weatherability. Without this coating, they offer lower performance due to not being resistant to denting nor certain chemicals.
	Leather production -	Silicon-based anti-soiling auxiliary	Manufacture of leather articles	Similar performance for anti-soiling properties with exception to resistance to coffee.
Renewable Energy	-	Pb (Lead acid) battery	Batteries	Lead batteries are around one third heavier than lithium-ion batteries in which FPs are used.
	-	High temperature fuel cells	Fuel Cells (stationary applications)	The key disadvantage, compared to PEM fuel cells is that they can only be used in stationary applications.

3. REGULATORY MANAGEMENT OPTIONS (RMOs)

The need to evaluate possible RMOs for FPs is not derived from concerns related to FP substances as such. Even though FPs match the definition of PFAS based on structure alone, they have different toxicological and ecotoxicological properties. The main FPs are regarded as PLC, and they exhibit only properties of persistency which, according to the REACH Regulation, does not in itself justify additional regulatory actions on a substance. However, impacts related to other substances that may be carried over through the supply chain as a result of the manufacturing process (residual PFAS used as polymerization aids, free monomers or oligomers, or other by-products), or substances that may be generated during end-of-life treatment (greenhouse effect gases) may generate situations of concern.

Acknowledging that it is relevant and necessary to address those concerns, it is advisable to explore possible RMOs that could be useful for this purpose, and to select the one(s) that will be more efficient and proportionate with current and future societal needs in the EU. For this reason, a process to identify, assess and recommend the most adequate RMO is performed in this RMOA.

3.1. Identification of RMOs

In order to address a concern related to a substance or group of substances, a variety of RMOs can be considered. The different legislative measures that may be used will have specific strengths and weaknesses which will vary depending on the case. The aim of a systematic analysis of the RMOs is to facilitate the identification and choice of the most appropriate measure (or combination of measures) for the case at hand. In a first step, a number of RMOs that could be regarded as potentially feasible to address the concerns related to the chemicals subject to the RMOA will be screened. Depending on the specific considerations for the substance(s) under discussion, some of these initially screened RMOs may be regarded as not viable for further assessment and will be therefore dropped for in-depth analysis.

Table 41 shows the preliminary screening of RMOs that could be relevant for FPs, their initial assessment, and the conclusion on whether the RMO needs to be further evaluated.

Table 41. Preliminary screening of RMOs

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 that are out of scope of other RMOs	YES

Related to the option of registration under REACH, it is to be noted that as of today, polymers are exempted from the obligation to register. However, this disposition may change in the future, as this is being evaluated by COM (Chemical Watch, 2019 and CARACAL, 2020). FPs were mentioned in a report prepared for COM on the possibility to identify and group polymers for registration (Wood, 2020). In the report FPs are cited as generally meeting the criteria to be identified as PLC. While it is not excluded that FPs may be identified in the future as Polymers Requiring Registration (PRR), this legal requirement would not exclude the possibility that FPs could be included in a restriction proposal or any other regulatory procedures (as is the case for any chemical substance in scope of the REACH Regulation). It is anticipated that any future obligation to register polymers that could include FPs would not bring significant improvements in terms of risk control of the concerns identified for the manufacture and use of these polymers. For this reason, this option is not evaluated further in this RMOA. Furthermore, it could be argued whether registration can in itself be regarded as an RMO. Indeed, as highlighted in the ECHA Integrated Regulatory Strategy (ECHA, 2021c) registration should be regarded as a source of information for further regulatory action, along with other possible data references (e.g., notifications to the ECHA C&L inventory).

As for the update of other EU legislation on specific sectors of use, it should be highlighted that, while this option would appear to be feasible in practice, as mentioned previously this could be redundant if adequate measures to control the manufacturing process of FPs are introduced. If new requirements are added to such legislation (e.g., introducing limits of contents or emissions of specific substances that may be originated in the FP manufacturing process), it is expected that, in practice, producers of articles containing FPs will request the FP manufacturers to deliver materials that will ensure compliance with the updated legislation. This will need to be certified by controlling the presence of those specific substances in the final FP products. Obviously, updating specific legislation could be a complementary tool that may be useful in some sectors, however the primary goal should be to address the concerns at the manufacturing stage.

Restrictions are an instrument to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels. A restriction may apply to any substance on its own, in a mixture or in an article, including those that do not require registration, for example, substances manufactured or imported below one tonne per year or certain polymers (ECHA, 2021a). A restriction can be triggered on a substance when it is demonstrated that there are risks that need to be addressed on a Community-wide basis. According to the REACH Regulation, a restriction must be targeted to the effects or exposures that cause the risks identified, it has to be capable of reducing these risks to an acceptable level within a reasonable period of time, and it must be proportional to the risk.

A Member State, or ECHA, at the request of COM, can start the restriction procedure when they are concerned that a certain substance poses an unacceptable risk to human health or the environment, which requires action on a Community-wide basis. Following the communication of the intention to prepare a restriction proposal in the Registry of Intentions, a restriction dossier is prepared by the interested party. The dossier will then be subject to different phases, involving public consultations and opinions from the relevant committees (RAC, SEAC) before COM takes a decision and the restriction is enforced.

When evaluating the possibility to include FPs in the PFAS restriction proposal, it needs to be reiterated that, as described previously, while FPs may meet the (broad) definition of PFAS in terms of their chemical structure, it is questionable that their hazard and risk properties could be compared to those exhibited from other materials of high concern that are included in that group. However, other considerations related to indirect risks derived from manufacture, use and disposal of FPs may lead regulators to consider regulating FPs jointly with other PFAS.

Following the results of the preliminary screening as shown in Table 41, the RMOs that will be analysed in this section are:

1) REACH Restriction of PFAS without derogations for FPs (RMO 1).
2) REACH Restriction of PFAS with partial derogations for FPs (RMO 2).
3) Voluntary Industry Initiative to address concerns related to manufacture (equivalent to a REACH Restriction of PFAS with broad derogations for FPs) (RMO 3).
4) Updates to EU legislation related to end-of-life considerations of FPs (RMO 4).

3.1.1. RMO 1: REACH Restriction of PFAS without derogations for FPs

Under this RMO, it is assumed that FPs as such and their relevant monomers would be included in the scope of the PFAS restriction. Furthermore, this scenario will also assume that the restriction conditions would lead to a complete elimination of manufacture, import and uses of FPs in the EU, either because they are directly banned, or because the conditions established under potential derogations (e.g., for the continued use of PFAS as polymerization aids) render the continuity of manufacture of FPs impracticable for industry. In this scenario, it is assumed that this would have a knock-on effect on the supply chain which would result in the practical termination of all uses of FPs.

3.1.2. RMO 2: REACH Restriction of PFAS with partial derogations for FPs.

This RMO will evaluate a situation by which FPs as such and their related monomers are not restricted under the PFAS restriction (e.g., via derogations). However, the use of PFAS-based polymerization aids that play a key role in the manufacture of certain FP grades would be banned. Furthermore, the restriction would include conditions in relation to the purity of FP products that may be used in the supply chain, for example in terms of maximum concentrations allowed of remaining monomers, polymerisation aids oligomers or other by-products resulting from the manufacturing process. Systems to ensure that these conditions would be applicable to imported FPs should be included in this RMO.

It is to be noted that, at present time, PFAS-based polymerization aids are only used in certain types of emulsion polymerization processes, while they are not used for suspension polymerizations. Moreover, as stated by some manufacturers of FPs in the replies to the survey conducted for this RMOA, progress has been made to remove the use of PFAS even from emulsion processes involving some specific FPs. Still, in many cases PFAS-based polymerization aids or PFAS-based solvents are required to achieve ultra-high molecular weights which are needed to obtain the required properties. This includes the critical sectors of chemical industry, aerospace, automotive, medical devices, pharma applications, semiconductors, etc. At the present time it is not possible to completely remove fluorinated polymerization aids from these manufacturing processes.

In parallel, it is relevant to highlight that, as it has been confirmed via different replies to the RMOA questionnaire received from manufacturers, importers and DUs, the FP business is characterized by its very high capital intensity. FPs are manufactured in a closely interrelated network of operations, which requires utilization of the overall network to ensure their profitability. For this reason, the FP manufacturing industry expects that potential bans on one or multiple FPs may render the overall FP business unprofitable in the EU, which could lead to termination of business in many cases.

3.1.3. RMO 3: Voluntary Industry Initiative - REACH restriction with broad derogations for FPs.

The starting point of this RMO will be a situation under which FPs are not directly impacted by the PFAS REACH restriction, either because they are left out of the scope of the restriction, or because a wide derogation is introduced for them. In addition, derogations would be in place for monomers and for PFAS used as polymerization aids in the manufacturing process of FPs. These conditions would be linked to an agreement by the FP industry to commit to a Voluntary Industry Initiative (VII) aimed at addressing the main concerns related to the manufacture and use of FPs. In addition, as described in RMO 2, strict procedures should be put in place by the regulators to guarantee adequate control of imported FPs to ensure a level playing field between FP products manufactured in the EU against those imported from other regions.

A VII refers to private efforts undertaken by a company or industry sector to improve performance related to health and environmental concerns, in order to achieve specific standards, or to go beyond existing legal requirements (Paton, 2000). A VII consists of a set of technical and managerial actions agreed by industry, by which all the members participating in the initiative commit to achieving certain goals within a specific timeframe, with the objective to eliminate or reduce a risk or a specific situation of concern, as far as technically practicable. A VII needs to be clearly elaborated and the expected actions must be outlined in a transparent way. Mechanisms to ensure that the actions are implemented within the agreed timeframe must be clearly outlined to allow monitorability of the progress. Ultimately, systems to measure the risk reduction achieved need to be put in place, to allow comparison with the original objective. These systems have to be open for verification by regulators. A relevant example for FPs on similar initiatives is the US EPA PFOA Stewardship Program (US EPA, 2006).

In the case of FPs, the risk during manufacture and use appears to be adequately identified and limited to the use of certain PFAS under specific conditions in the manufacturing process (as polymerisation aids only in certain type of reaction processes), and to the potential presence of monomers, oligomers or other by-products in the final FP product that may be placed on the market. Under the VII RMO, it would be expected that those PFAS would be derogated from the broad REACH restriction, as long as their use is adequately controlled during the manufacturing process of FPs and the subsequent uses of these FP products, allowing for continued use in the EU. Industry would be expected to introduce all the necessary technical and operative measures that are technically available to grant the minimisation of exposure, while they continue to put R&D efforts in place to completely remove the use of PFAS as polymerization aids in the future[11]; the VII should operate under the assumption that, when such alternatives are identified and proven to be viable (e.g.

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[11] While the FP industry has been successful in removing PFAS from the manufacturing process of certain FP types, it should be acknowledged that this may not always be possible for every type or grade of FPs.

resulting in equivalent technical performance, reducing the overall risk of the process, and as long as they are available in sufficient quantity and at reasonable cost), those PFAS will be phased out from the manufacturing processes. Those technical actions would be expected to ensure recovery of PFAS to the maximum possible technical level, and to minimise their release to the environment. Actions should be initiated to reduce to a minimum the presence of monomers, oligomers or other by-products derived from the manufacturing process in the final FP products to be placed on the market.

The content of the VII should be discussed and eventually agreed between industry and regulators. As a part of this process, it is to be expected that specific regulatory updates will be introduced in relevant EU legislation and manufacturing permits that would articulate such agreements. This could come, for instance, via updates to the Industrial Emissions Directive, in a way that would reflect the conditions agreed, and which would bring emissions from the manufacturing process of FPs to levels that are regarded as acceptable. In a similar way, wherever relevant side EU legislation on specific end uses (e.g., regulations dealing with water, food packaging, electronics), may be updated as well, based on the holistic, comprehensive, and ambitious emission reduction objectives within which industry could operate.

It is to be noted that at the time of developing this RMOA, there is no specific information available on the technical terms that will be the basis for this VII. The content of the VII will be agreed among the FP manufacturing companies within the FPG and discussed with the relevant EU competent authorities, to ensure an adequate commitment with the objective to remove or minimise concerns related to manufacture and use of FPs, including a transparent system for evaluating and monitoring progress.

The evaluation that is performed under this RMOA is based on the assumption that the VII option will be adequately designed and implemented, and that it will bring the expected outcome that the FPG members will commit to in terms of adequately controlling any risks remaining derived from the manufacture and use of FPs in the EU.

It is worth highlighting that the FPG has recently created a Responsible Manufacturing Task Force (RMTF), with the objective to develop the content of the VII. A first proposal that the FPG has put together, described as a Responsible Manufacturing Commitment which will be further developed in the coming months, can be found in Annex IV.

3.1.4. RMO 4: Updates to EU legislation related to end-of-life considerations of FPs.

FPs are used in a wide variety of industrial processes, and they are present in many articles that are used by consumers (e.g., vehicles, electronics, cookware). Given that some of those articles are extremely complex, in which FPs may be present in small parts combined with other type of chemicals or materials, recycling and recovery of FPs will not always be possible nor practicable. For this reason, significant amounts of FPs may be landfilled and incinerated, which could result in releases to the environment of decomposition products. However, it is also worth noting that, in the context of the recent EU initiatives such as the Green Deal (European Commission, 2021a), circularity and ability to recover materials from waste streams will play a key role in future EU policy and technological developments. Therefore, it is to be expected that relevant stakeholders will place efforts to maximise recovery of FPs from waste.

Since waste is not covered under the REACH Regulation, specific regulatory actions would be required to ensure that the risks derived from such emissions are adequately controlled. These actions should be implemented via revision of the relevant legislation applicable to waste streams, introducing methods to guarantee that decomposition products from end-of-life of FPs do not pose unacceptable risks. Moreover, while FPs are persistent, they are inert chemicals that are not toxic, nor do they bioaccumulate, therefore landfilling would likely not result in significant risk. However, possible by-products present in final FP products, generated during the manufacturing process of FPs (residual monomers, oligomers, remaining PFAS polymerisation aids) may bring unexpected risks to waste streams that should be tackled via improving landfill conditions.

Specific legislative pieces that could be reviewed in order to incorporate additional protective elements for humans and the environment from the release of potentially hazardous decomposition products from disposal of FPs are[12]:

- Industrial Emissions Directive (Directive 2010/75/EU).
- Waste Incineration Directive (2000/76/EC).
- European Pollutant Release and Transfer Register (E-PRTR).
- Waste Framework Directive (Directive 2008/98/EC).
- Landfill legislation (Directive 1999/31/EC).
- Water Framework Directive (Directive 2000/60/EC).
- End-of-Life Vehicles (Directive 2000/53).
- Waste Electrical and Electronic Equipment (WEEE Directive 2002/96/EC).
- Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2011/65/EU).

It is to be noted that this RMOA does not intend to go into full detail of specific technical requirements and legislative changes that would be required in specific legislation dealing with end-of-life of FPs. As it has been explained in section 2.3.3, there is available literature providing indications on the main aspects to consider in relation to FPs and waste treatment (PlasticsEurope, 2012), including potential substances that may result as by-products from incineration (Aleksandrov, 2019), existing techniques (Pro-K Fluoropolymergroup, 2018), or

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[12] Non-exhaustive list; amendments to be considered where relevant.

modern technologies to perform Up-cycling for recovery of monomers from disposed FP products (Schlipf and Schwalm, 2014). It is expected that regulatory requirements for continued review of the state of the art at waste treatment facilities will be developed, related to improving collection and treatment of waste by-products derived from incineration of FPs, or to evaluate technical options to ensure that landfilling of waste will not lead to negative environmental effects. In fact, it has been already indicated that legislative actions will likely be needed to deal with waste and end of life treatment to cover risks of PFAS, independently of the progress of a REACH restriction or any other regulatory action dealing with manufacture and use of these substances (European Commission, 2020a). Therefore, it can be assumed that such actions will be implemented in the near future at EU level, and that they will provide adequate improvements in the control of emissions of by-products from FPs to the environment.

3.2. Assessment of RMOs

The RMOs (1 through 4) that have been identified and considered relevant for further assessment will be evaluated according to a specific methodology. Details on this methodology can be found in Annex I. Essentially, the different RMOs are analysed in relation to a series of criteria, in order to provide conclusions in relation to their effectiveness, practicality, broader impacts and regulatory consistency. Under these four criteria, different independent factors are evaluated, and each RMO analysed will be assigned a score (within the range +3 to -3) depending on the degree to which it is estimated that the RMO would impact on the factor, either positively or negatively. Finally, a series of weighting corrections are applied, depending on how significant the factors and criteria are expected to be in relation to the overall objective of applying the RMO. These corrections are consistent across the different RMOs evaluated, i.e., the same weighting is applied to the factors that are evaluated, irrespective of which RMO is analysed.

3.2.1. Effectiveness – Risk reduction capacity

Under a full restriction (RMO 1), likely leading to a complete elimination of FPs in the EU, it appears evident that any risk that could be related to these materials would be removed from Europe. It is expected that in the long term eventually all articles containing FPs would disappear from the EU market, thus leading to a total removal of risks. This RMO is considered as the one to achieve the highest capacity to reduce risk. In the case of a partial restriction (RMO 2), since this would be limited to the cases of greater concern, i.e., removing the use of PFAS from the manufacturing process of FPs, it is assumed that this option would have a significant but slightly lower risk reduction capacity as a full restriction. Based on the conditions from derogations, this option would be expected to address other issues, such as controlling the residual levels of monomers, oligomers or other by-products that may remain in the final FPs manufactured. This RMO would not deal with end-of-life emissions though.

In relation to a VII, it is expected that RMO 3 would achieve a good level of risk reduction, yet not at the level of the other restriction options as some uses of PFAS substances used in the manufacturing process of FPs would be allowed; indeed, it has to be accepted that 100% risk removal values can only be achieved via full closure of the activity. In any case, because the sources of risk from the manufacture and uses of FPs are clearly identified, a thorough commitment from the FP industry would result in continued improvements in terms of risk reduction. It is to be noted that significant progress has already been achieved in removing or minimising the use of PFAS from the manufacturing process of FPs (even in the emulsion polymerisation, which is traditionally considered as being 100% dependent on fluorinated surfactants), as well as regarding recovery of used material or minimisation of free monomers and oligomers. This progress is being achieved via continuous investments from the FP manufacturing companies, which have already been effectively developed over the past 10+ years in ranges of tens of millions of euros by individual companies.

Considered on its own, the update of EU legislation as outlined under RMO 4 related to waste and end-of-life, with the aim to introduce specific requirements for FPs would have a very relevant impacts, yet limited to the specific sector of action, because this would not tackle potential risks resulting from manufacture and use. This would take care of emissions of dangerous by-products resulting from the incineration and landfilling of articles (mostly complex ones) that contain FPs.

Scoring of each RMO under the “Risk reduction capacity” factor is assigned as follows:

- RMO 1: Full restriction: high positive impact (+3)
- RMO 2: Partial restriction: medium/high positive impact (+2/+3, average +2.5)
- RMO 3: Implementation of the VII: medium positive impact (+2)
- RMO 4: Updates to existing EU legislation on waste treatment: low/medium positive impact (+1/+2, average +1.5)

3.2.2. Effectiveness – Measurability / Monitorability

Related to how feasible it would be to monitor or measure progress of each RMO, it is considered that it would be relatively straightforward for all the RMOs evaluated to satisfactory fulfil this factor. In the case of a full restriction (RMO 1), systems to verify the progressive reduced volumes of FPs manufactured and likely imported in the EU would be the first obvious control parameter, however a partial restriction including derogation of FPs and their monomers (RMO 2) may require some additional efforts to verify the purity of FP products placed on the market, which could involve some practical and technical challenges.

For a VII (RMO 3) and the update of existing EU waste legislation (RMO 4), it is assumed that industry is already implementing monitoring controls on emissions of fluorinated products, or at least those controls are technically available, nevertheless some adjustments will likely be required, and strict reporting systems will need to be developed and implemented. Following an evaluation of the replies received to the RMOA questionnaire delivered to with industry, it is confirmed that all manufacturers of FPs include systems to monitor emissions, and that most of the DUs are in a position to do this wherever relevant. From the information that is available in literature, a parallel situation would be expected for waste treatment plants. However, it is likely that more stringent reporting procedures to allow monitorability would be required.

Scoring of each RMO under the “Measurability / monitorability” factor is assigned as follows:

- RMO 1: Full restriction: high positive impact (+3)
- RMO 2: Partial restriction: medium/high positive impact (+2/+3, average +2.5)
- RMO 3: Implementation of the VII: low positive impact (+1)
- RMO 4: Updates to existing EU legislation on waste treatment: low positive impact (+1)

3.2.3. Effectiveness – Time until implementation

It should be expected that both restriction options (RMO 1 and RMO 2) would achieve the risk reduction objectives ahead of any other possible RMO. The time when the restriction should become fully effective would be fixed by EU Authorities, therefore this would be regarded as the most effective possible time to meet the risk reduction requirements from these RMOs. On the other hand, RMO 3 and RMO 4 would likely require more time to implementation, as this would involve the need to introduce upgraded technical measures in most of the industrial establishments concerned, which would imply that industry stakeholders should become partners and co-drivers of the process. This would be probably more evident in the case of waste treatment sites because the manufacturers of FPs are likely more aware of the technologies that will be needed. In any case, it is expected that the required upgrades could be achieved within reasonable periods of time.

Scoring of each RMO under the “Time to implementation” factor is assigned as follows:

- RMO 1: Full restriction: high positive impact (+3)
- RMO 2: Partial restriction: high positive impact (+3)
- RMO 3: Implementation of the VII: low/medium positive impact (+1/+2, average +1.5)

- RMO 4: Updates to existing EU legislation on waste treatment: low positive impact (+1)

3.2.4. Practicability – Implementability

When evaluating the implementability of an RMO, it is necessary to assess how feasible it is for all the relevant actors to undertake the necessary actions to comply with its requirements. In the case of a full restriction (RMO 1), in order to implement this RMO, many industrial sites in the EU would need to terminate their business and shut down their operations. This is expected to impact 100% of FPs manufacturers in Europe, and likely a very high number of DUs. Due to the lack of alternatives for the majority of uses of FPs (most of which are critical for society), it can be expected that significant distress would be created throughout the supply chain of FPs. Actions related to closure of sites, in terms of termination of labour contracts, dismantling of installations, actions with local authorities, or relocation of operations, just to name a few, would have to be undertaken by the relevant stakeholders.

A similar situation could be expected under RMO 2 (partial restriction with derogations for FPs and their monomers), however in this case some FP manufacturers may continue their activity, but important FP products for key European industries are expected to leave Europe. It is expected that most of those manufacturers would have major issues to continue operations in Europe and would likely need to terminate the business. Knock-on effects could be expected due to the very high capital intensity of the FP business, by which it is assumed that negative impacts on some types of FPs derived from a restriction could impact business continuity for those that may be covered by derogations, including reorganization of manufacture and closure of some sites, as extracted for some of the replies obtained from the RMOA questionnaire. However, since the manufacture of FP products that do not require PFAS as polymerization aids could continue via derogations, this RMO would not be as critical as RMO 1, as it is expected that industry may find ways to continue manufacturing and marketing those FP products.

Actions related under the other RMOs evaluated would appear to be less demanding. Under RMO 3 and RMO 4, it is expected that upgraded technical measures will need to be implemented to achieve the risk reduction objectives. Following an evaluation of the replies received to the RMOA questionnaire, particularly among the manufacturers of FPs, references were made to the use of e.g., regenerative thermal oxidizers (RTO) with caustic scrubber for air emissions, and activated carbon adsorption beds to treat water effluents, or up-cycling systems to obtain monomers that can be reused in the manufacturing process from waste FP products. While other actions may be required, the commitment by industry to ensure continuity of business would be expected to overcome the technical challenges. However, it cannot be excluded that some actors may have more difficulties than others to introduce the required technical upgrades. For those that have already implemented these upgrades, or have developed individual company commitments in this line, this factor would not result in neither positive nor negative impact and a baseline scenario should be assumed. In the case of operators of waste treatment plants, it is likely that implementability may result in certain challenges, however those should be low, since the technology required by the regulatory updates should be in line with other risk management measures that these sites are used to implementing.

Scoring of each RMO under the “Implementability” factor is assigned as follows:

- RMO 1: Full restriction: high negative impact (-3)
- RMO 2: Partial restriction: medium negative impact (-2)
- RMO 3: Implementation of the VII: low negative/neutral impact (-1/0, average -0.5)
- RMO 4: Updates to existing EU legislation on waste treatment: low negative impact (-1)

3.2.5. Practicability – Enforceability

While some of EU Member States have experience in the enforcement of restrictions on chemicals after more than 10 years of implementation of REACH, there is variability in the degree of expertise and resources available among different Competent Authorities. ECHA’s Forum for the Exchange of Information on Enforcement has developed tools and guidance to support Member States in this task (ECHA, 2021d). In the case of a full restriction impacting FPs (RMO1), the overall contribution from this factor would be expected to be positive, to a medium extent. It should be relatively straightforward to implement a restriction that would cover all FPs available in the EU market. While a similar reasoning could be put forward in the case of a restriction with derogations (RMO 2), it needs to be noted that this could introduce additional challenges. Since the derogations would imply conditions in terms of composition of FPs to be placed on the EU market, controls for evaluating imported FP products from non-EU countries would need to be put in place, to ensure that only products with equivalent levels of composition enter the EU territory as those manufactured internally.

Enforceability of the VII (RMO 3) could have a similar behaviour in comparison to RMO 2. On one hand, the number of FP manufacturing sites in the EU is less than ten, and the actors involved are well known, which would make it easy for regulators to control the implementation of the commitments under the VII. This could be verified for instance, via the introduction of reporting requirements, as has already been done for other cases, such as the restriction on intentionally added microplastics (ECHA, 2019). In addition to this, the FP industry has already demonstrated willingness to cooperate with regulators, for example under the PFOA Stewardship Program by EPA (EPA, 2021).

In addition to this, it is to be noted that in order for the VII to be efficient, similar levels of rigor should be demanded to FP products imported from non-EU manufacturers. Mechanisms should be put in place to guarantee that DUs of FPs will only have access to FP products that are manufactured according to the standards set in the VII, therefore blocking access to imported FP products of lower purity, or which have been manufactured with lower technical standards and may pose risks to DUs and the environment. This would likely require the adoption of measures to periodically evaluate and report on progress achieved in the goals established via the VII, so that similar standards to be demanded on imported FP products are updated within a reasonable timeframe. In any case, this requirement would be similar to that required under RMO 2, so both RMOs could be seen as having a low positive impact against this factor.

In relation to the enforcement of EU legislation dealing with end of life of FPs (RMO 4), it is assumed that EU authorities would be capable to enforce the updates to relevant legislation on waste treatment, to adequately control emissions of fluorinated by-products from facilities in this sector.

Scoring of each RMO under the “Enforceability” factor is assigned as follows:

- RMO 1: Full restriction: medium/high positive impact (+2)
- RMO 2: Partial restriction: low/medium positive impact (+1)
- RMO 3: Implementation of the VII: medium/low negative impact (+1)
- RMO 4: Updates to existing EU legislation on waste treatment: medium/high positive impact (+2/+3, average +2.5)

3.2.6. Practicability – Manageability

The management of a restriction impacting FPs in the EU would create a challenge in terms of manageability. Many respondents to the DU survey conducted in preparation of this RMOA have expressed their concern that they may not be capable to operate under the conditions that could be imposed in a restriction, particularly if that limits the access to FP products of the required quality for their uses. The tremendously complex supply chains involved in most of the industrial sectors in which FPs are used would make it very difficult to ensure a smooth management of this RMO. This would still be the case even if derogations to certain FPs were included in the restriction, due to indirect impacts that the involved supplied chains may suffer, however it can be assumed that those derogations could make things somewhat easier for those actors.

On the other hand, working under the conditions set in the RMO 3 would provide certainty to the DUs of FPs, and to the manufacturers themselves. While it is recognised that there may be challenges to meet the commitments that industry would undertake under this RMO, the fact that this is a highly innovative industry, used to undertaking continued improvement actions on a number of areas (related to safety, but not only), would probably facilitate a successful management of this RMO.

A similar reasoning could be made for the management of new requirements under existing EU legislation on waste (RMO 4). The technical improvements that would be enforced by regulators could increase the level of complexity for the waste treatment industry, however this should not result in unmanageable conditions of operation.

Scoring of each RMO under the "Manageability" factor is assigned as follows:

- RMO 1: Full restriction: high negative impact (-3)
- RMO 2: Partial restriction: medium negative impact (-2)
- RMO 3: Implementation of the VII: low positive impact (+1)
- RMO 4: Updates to existing EU legislation on waste treatment: low positive impact (+1)

3.2.7. Broader Impacts – Additional human health or environmental impacts

As described in Section 2.4, a wide range of applications of FPs are critical for ensuring adequate human health and environmental protection. FPs are key components required to guarantee safety of industrial installations in chemical and power plants, in transport systems like aircrafts, in professional clothing for firefighters or aerospace suits, in ensuring high quality production of pharmaceuticals or medical devices, just to name a few. In addition, FPs contribute significantly to achieving adequate control of environmental emissions from many sources, such as vehicles, chemical plants, and fossil-fuel power plants. FPs are considered to be critical for developments of alternative energy sources like lithium-ion batteries, solar panels, or hydrogen fuel cells. Any restriction (RMO 1 and RMO 2) that could limit the availability of FP products for those sectors in Europe would result in highly severe negative impacts to human health and the environment. In this regard, most (but not all) of the FP grades that are critical in safety applications are those that, as of today, still require the use of PFAS polymerization aids, therefore those uses would be impacted even by a partial restriction. Furthermore, it is expected that any uncertainty that could be generated on the future availability of FP products, coming either via a full or partial restriction, would result in barriers to the development of innovative technologies in these key sectors.

In relation to a VII, the outcome of the implementation of the RMO 3 would be similar to a "business as usual" case, in the sense that the FP technology would remain available for those key applications related to preservation of health and the environment. However, due to the impact that the actions related to implementation of the VII are expected to have in R&D initiatives (in line with the historical innovative development of the FP industry), it can be assumed that a long-term outcome of this RMO would result in even more efficient FP products, which will bring an overall improvement of the technologies in which they are applied.

A similar reasoning can be applied to the update of existing legislation dealing with end-of-life of FPs under RMO 4. Independently from direct risk reduction from the treatment of FPs in e.g., incineration plants, it is expected that any technological upgrade to deal with by-products of FPs may give rise to opportunities to improve human health and environmental conditions related to other chemicals.

Scoring of each RMO under the “Additional human health or environmental impacts” factor is assigned as follows:

- RMO 1: Full restriction: high negative impact (-3)
- RMO 2: Partial restriction: high/medium negative impact (-3/-2, average -2.5)
- RMO 3: Implementation of the VII: neutral/low positive impact (0/+1, average +0.5)
- RMO 4: Updates to existing EU legislation on waste treatment: neutral/low positive impact (0/+1, average +0.5)

3.2.8. Broader Impacts – Socio-economic impacts

Argumentation under this factor is very similar to the previous one. The socio-economic impact of the use of FPs is significantly high in the EU, related to many key industrial sectors which eventually result in inclusion of FPs in articles that have become fundamental to ensure not only a high-quality level of life in the EU, but also the basic functioning of a modern society. In this regard, it is expected that any alteration to the accessibility of the necessary high quality FP products would have an extremely negative socio-economic impact in the EU, with great damage to the competitiveness of certain critical economic sectors. This would be even more acute in the case of a full restriction (RMO 1).

It could be argued that certain socio-economic benefits could be derived from a restriction on FPs. This would be related to avoiding costs of remediation of pollution related to emissions from the FP manufacturing process for example. While it is not in the scope of this RMOA to fully quantify and compare the positive economic impacts of a restriction with the negative ones, taking into consideration the relatively low manufacturing volumes of FPs in the EU, compared to the wide variety of critical applications in which FPs are involved, it is expected that the potential benefits from a restriction (RMO 1 and RMO 2) would remain very far from compensating the losses that society would face if access to FPs were to be limited.

In contrast, the implementation of the RMO 3 would guarantee the continuity of those uses. Furthermore, it is expected that certain benefits will be derived from the continued effort placed on innovation for finding more sustainable and therefore more efficient FP products.

This option would also result in reduced remediation costs since the control on emissions would continue to improve. It is true that there will be cost for FP manufacturers, however those costs will result in revenue for other industries (e.g., those providing the required technologies for improved control of emissions), so those costs would be compensated. A parallel assessment can be done in relation to the update of existing EU legislation on waste (RMO 4). Ultimately, for both RMOs a situation similar to the baseline (current state of the art) or with a slight improvement could be expected.

Scoring of each RMO under the “Socio-economic impacts” factor is assigned as follows:

- RMO 1: Full restriction: high/medium negative impact (-3/-2, average -2.5)
- RMO 2: Partial restriction: medium negative impact (-2)
- RMO 3: Implementation of the VII: neutral/low positive impact (0/+1, average +0.5)
- RMO4: Updates to existing EU legislation on waste treatment: neutral/low positive impact (0/+1, average +0.5)

3.2.9. Regulatory consistency - Consistency with existing EU legislation

Any regulatory initiative that brings FP substances to the same level of regulatory scrutiny as other PFAS, some of which are known to pose risks for human health and the environment, cannot be regarded as being consistent from the legislative point of view. As described in Section 2.1.1, FPs are stable, biologically inert, not soluble in water and therefore not mobile. The main FPs (accounting for 70-75% of consumption) have been demonstrated to meet the criteria established by the OECD on PLC and as such they do not pose significant risks to human health or the environment.

While FPs may meet the REACH definition to be considered persistent substances (durability is a highly desirable property in many FP products and applications that are critical for safety, as this is strongly linked to chemical inertness and stability) and acknowledging that this property may warrant further consideration in terms of potential environmental evaluations, persistency alone does not imply that there is a present or future risk to human health or the environment. REACH has regulated persistence so far in the context of PBTs and vPvBs where Persistence (P) must be associated with other relevant properties (Bioaccumulation, Toxicity) to justify considering a substance as being of concern. There is no indication in REACH that Persistence alone justifies risk management measures. Furthermore, FPs are not mobile in the environment given their negligible solubility and have been demonstrated to have no systemic toxicity. Taking this into consideration, the full restriction (RMO 1) is evaluated as being negative against this factor with a medium impact.

On the other hand, a restriction with derogations (RMO 2) that would tackle situations of concern related to manufacture and final composition of FPs cannot be claimed as going against the principles of existing legislations in the EU and it fits well in the general scheme of the REACH Regulation. It is to be noted that RMO 3, related to a VII, could in its origin be based on a REACH restriction with broad derogations. While it could be claimed that an RMO that depends on an industry initiative to handle risks would not be at the same level of regulatory consistency as other options, it should still be regarded as showing a positive impact under this factor, as long as it is adequately defined, implemented and controlled.

Finally, related to the update of existing EU legislation impacting waste treatment of FPs (RMO 4), it is evident that any action resulting in improvement and further development of such legislation would be completely aligned with this factor, resulting in the highest possible score.

Scoring of each RMO under the "Consistency with existing EU legislation" factor is assigned as follows:

- RMO 1: Full restriction: medium negative impact (-2)
- RMO 2: Partial restriction: medium/high positive impact (+2/+3, average +2.5)
- RMO 3: Implementation of the VII: low positive impact (+1)
- RMO 4: Updates to existing EU legislation on waste treatment: high positive impact (+3)

3.2.10. Regulatory consistency - Consistency with other EU policy objectives

COM has recently developed an ambitious plan to achieve no net emissions of greenhouse gases by 2050 via the so-called Green Deal (European Commission, 2021a). FPs play a critical role in achieving this objective, as well as those from the UN Sustainable Development Goals (United Nations, 2021), since they are key components of renewable energy installations (e.g., lithium-ion batteries, solar panels), and of green hydrogen production options which are relevant to achieve the 13% target for clean 'green' hydrogen in the energy mix by 2050 (European Commission, 2020c). Furthermore, FPs are critical components in vehicles to increase engine efficiency thus reducing exhaust emissions.

Under this premise and considering the lack of viable alternatives that would ensure the levels of efficiency that FPs exhibit in these applications, it appears to be evident that any action aimed at restricting the availability of FPs on the EU market would play against the achievement of the goals set in the EU Green Deal. It could be claimed, however, that the elimination of potential sources of fluorinated by-products to the environment would itself be in line with global EU environmental objectives. In any case, it is expected that the balance between positive and negative impacts of a full restriction (RMO 1) would be clearly negative. Under a partial restriction (RMO2), it could be possible to justify some consistency with EU regulatory objectives, but overall, the measure could be expected to show a low negative impact in relation to this factor, as the balance between positive effects and indirect impacts on other EU policy objectives may result in a limitation for achieving such goals.

In contrast, the implementation of the VII (RMO 3) and the revision of existing EU legislation on waste treatment (RMO 4) would be fully aligned and consistent with the long-term objectives from the EU in terms of reducing pollution, and to boost innovation for safe and sustainable chemicals (it is to be noted that innovation is expected to be a key component of the VII).

The implementation of a VII as outlined in Section 3.1.3 would appear to be a much more consistent way of dealing with risks associated to manufacture and uses of FPs. This is completely aligned, for example, with the concept of “Better Regulation” which is one of the top priorities of the EU (European Commission, 2021c). Indeed, a thorough development of the commitments that the FP industry is willing to undertake would lead to the implementation of an RMO that is fit for purpose, based on evidence, and which allows for stakeholder involvement in a transparent process.

Scoring of each RMO under the “Consistency with other EU policy objectives” factor is assigned as follows:

- RMO 1: Full restriction: high/medium negative impact (-3/-2, average -2.5)
- RMO 2: Partial restriction: low negative/neutral impact (-1/0, average -0.5)
- RMO 3: Implementation of the VII: high positive impact (+3)
- RMO 4: Updates to existing EU legislation on waste treatment: high positive impact (+3)

3.2.11. Overview of the scoring

Following the evaluation of all the RMOs identified as relevant, Tables 42 through 46 provide an overview of the scoring assigned to the RMOs for each evaluated factor. This scoring includes weighting corrections for factors and criteria, as outlined in the RMOA methodology described in Annex I, resulting in an overall score for each one of the RMOs. Standard weight factor is 1; for factors that are considered of higher importance, stronger weights are assigned, according to the following hierarchy:

- Risk reduction capacity: weight factor 2
- Additional human health or environmental impacts and Socio-economic impact: weight factor 1.50
- Measurability / Monitorability and Time to implementation: weight factor 1.25.

Table 42. Scoring of the RMO 1 Full Restriction.

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	+3	2.00	6.00
	Measurability / Monitorability	+3	1.25	3.75
	Timing to implementation	+3	1.25	3.75
Practicability	Implementability	-3	1.00	-3.00
	Enforceability	+2	1.00	2.00
	Manageability	-3	1.00	-3.00
Broader Impacts	Additional human health or environmental impacts	-3	1.50	-4.50
	Socio-economic impacts	-2.5	1.50	-3.75
Regulatory Consistency	Consistency with existing EU legislation	-2	1.00	-2.00
	Consistency with other EU policy objectives	-2.5	1.00	-2.50
	Overall RMO score			**-3.25**

Table 43. Scoring of the RMO 2 Partial Restriction.

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	+2.5	2.00	5.00
	Measurability / Monitorability	+2.5	1.25	3.13
	Timing to implementation	+3	1.25	3.75
Practicability	Implementability	-2	1.00	-2.00
	Enforceability	+1	1.00	1.00
	Manageability	-2	1.00	-2.00
Broader Impacts	Additional human health or environmental impacts	-2.5	1.50	-3.75
	Socio-economic impacts	-2	1.50	-3.00
Regulatory Consistency	Consistency with existing EU legislation	+2.5	1.00	2.50
	Consistency with other EU policy objectives	-0.5	1.00	-0.5
	Overall RMO score			**4.13**

Table 44. Scoring of the RMO 3 Voluntary Industry Initiative.

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	+2	2.00	4.00
	Measurability / Monitorability	+1	1.25	1.25
	Timing to implementation	+1.5	1.25	1.88
Practicability	Implementability	-0.5	1.00	-0.50
	Enforceability	+1	1.00	1.00
	Manageability	+1	1.00	1.00
Broader Impacts	Additional human health or environmental impacts	+0.5	1.50	0.75
	Socio-economic impacts	+0.5	1.50	0.75
Regulatory Consistency	Consistency with existing EU legislation	+1	1.00	1.00
	Consistency with other EU policy objectives	+3	1.00	3.00
			Overall RMO score	**14.13**

Table 45. Scoring of the RMO 4 Update of Existing EU Regulations on end-of-life.

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	+1.5	2.00	3.00
	Measurability / Monitorability	+1	1.25	1.25
	Timing to implementation	+1	1.25	1.25
Practicability	Implementability	-1	1.00	-1.00
	Enforceability	+2.5	1.00	2.50
	Manageability	+1	1.00	1.00
Broader Impacts	Additional human health or environmental impacts	+0.5	1.50	0.75
	Socio-economic impacts	+0.5	1.50	0.75
Regulatory Consistency	Consistency with existing EU legislation	+3	1.00	3.00
	Consistency with other EU policy objectives	+3	1.00	3.00
			Overall RMO score	**15.50**

3.3. Selection of RMOs

Based on the scores obtained in the previous section, it would appear evident that a full inclusion of FPs in the REACH restriction for PFAS (RMO 1) would not be a proportionate RMO. While it would be capable of addressing concerns related to the manufacture and use of FPs (to a higher or lower extent, depending on the conditions laid out in the restriction), significant negative impacts would result from implementation of this RMOs. 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 Green Deal of COM, not to mention the risks that would be created by losing key functionalities that FPs play in ensuring safety and protection in a variety of sectors, related to industrial uses but also to applications by consumers. A partial restriction (RMO 2) would not be as negative as a full restriction, but its positive impact would be estimated as low on average. By allowing continuation of some uses and manufacture of a limited set of FPs, the overall performance of this option, while not negative, would be far from the result that would be expected from an optimum option. In contrast, other RMOs like the VII (RMO 3), which would in any case be linked to the PFAS restriction, since the starting point would be a broad derogation of FPs, monomers and their relevant polymerization aids, or the review and update of relevant EU legislation dealing with end-of-life treatment of FPs (RMO 4) appear to be much more balanced in terms of effectiveness, broader impacts, and regulatory consistency.

It has to be noted that each RMO is evaluated taking into consideration the current state of the art for comparison purposes, in terms of regulatory pressure, uses and broader considerations. For example, it has been highlighted through this RMOA how critical the uses of FPs are in terms of ensuring adequate human safety and environmental protection, as benefits to be highlighted from the continued use of these FP products. However, the scoring of the VII (RMO 3) under the relevant factors analysed dealing with those considerations (‘Additional human health or environmental impacts’, and ‘Socio-economic impacts’) do not receive the highest possible score. This is because the outcome expected from implementation of the RMO is compared with the present situation – which is that those FP products are being used normally. The added benefit reflected in the score comes from the expected improvements in both factors from implementation and development of the VII conditions, which should bring enhancement of key applications of FPs via increased innovation, as well as from other expected benefits from lower costs related to remediation of pollution from emissions, which would be achieved via implementation of these RMOs.

Still, before establishing a final conclusion, it is recommended that a comparison should be done between RMOs. As outlined in the RMOA methodology described in Annex I, when evaluating a specific RMO (e.g., restriction), it is convenient to evaluate if this option is suitable, necessary, and proportionate, particularly in relation to whether any other alternative RMO would be available that would have a better performance. In the case of the inclusion of FPs in the REACH restriction of PFAS, it could be concluded that, while the RMO would be suitable for the purpose of reducing risks, it would not provide a good balance between the risk reduction and potential negative impacts to society. The fact that there are other RMOs available that could bring an acceptable degree of risk reduction should lead to the conclusion that those other RMOs should be preferred for regulatory purposes on FPs.

One additional item that needs to be taken into consideration is that some RMOs may have completely different ranges of application. While the update of existing EU legislation dealing with waste treatment would not address risks related to manufacture and uses from FPs, it is the only relevant RMO that would deal with emissions due to generation of by-products from end-of-life treatment of FPs; on the other hand, neither a restriction nor a VII would have any impact on potential risks related to disposal and final treatment of articles containing FPs. It is therefore advisable in these cases that a combination of RMOs is put forward, in order to maximise the benefits from each RMO in their relevant field of applicability.

For this reason, the conclusion from the evaluation of the different RMOs that could be applicable to FPs, is that a VII should be agreed with the relevant EU authorities and developed by the FP manufacturing industry. Efforts should be placed by the regulators in order to establish mechanisms that would ensure that imported FP products available on the EU market would meet equivalent quality standards expected from FP products manufactured in the EU, under the conditions established by the VII. This option would ensure minimization of PFAS used as polymerization aids (in any case to be used only when absolutely necessary, and with the aim to one day achieve full phase out of those substances, if technically feasible). In parallel, updates of relevant legislation covering waste treatment should be put forward in order to adequately control emissions from by-products related to end-of-life treatment of FPs.

3.4. Uncertainty

Different sources of uncertainty could influence the evaluation of the RMOs. In terms of items such as specific data on FPs (e.g., volumes, hazards, exposure, uses and alternatives) the most up to date sources of information have been used for the purpose of developing the RMOA, including information from literature and previous relevant work performed by industry and other parties. Efforts have been taken to try to refine and update this data, by performing a survey with the supply chain of FPs. Still, full accuracy of all the data used cannot always be guaranteed, particularly due to the significant complexity of the supply chains in which FPs are involved, and the vast applications and end-use articles in which FPs can be found. Moreover, the fact that polymers are (currently) exempt from the registration obligation under REACH makes it more difficult to have access to standardised datasets that are available for example for other substances that are subject to registration under REACH. The fact that most FPs meet the PLC criteria and are therefore considered to require limited attention from the regulatory perspective, plays against the possibility to have a robust set of studies on the FPs themselves (due to the fact that such data is likely unnecessary).

But beyond data accuracy, the most relevant sources of uncertainty come from the evaluation and assignment of scores to each RMO under the factors considered within the RMOA methodology. It is evident that, while the evaluation is performed in a rigorous and structured way, by trying to take all aspects into consideration that could impact the behaviour of one RMO under the analysed factor, the reasonings that lead to assigning scores are based on judgements undertaken by the evaluators. Ultimately, impact of the human factor on the evaluation cannot be neglected.

For this reason, the scores assigned to the different factors cannot be taken as absolute numbers, but as an orientation in comparison to the scale that has been used in the RMOA methodology. The indication of a range of values in some cases gives an idea on situations in which uncertainty has been identified, or in which a fixed answer to the question "how will the RMO perform under this factor" is simply not possible. A full and exhaustive quantification of positive versus negative impacts, where multiple and diverse consequences can be derived from the implementation of an RMO, are not within the scope of the RMOA, which is limited to a reasoned qualitative comparison between the different options.

Uncertainty can be narrowed if different RMOs are taken in combination, as described in Section 3.3. For example, in the case of a full restriction, in relation to the factor "Consistency with other EU policy objectives", a maximum negative score of -3 has not been assigned. Under this RMO, the expected outcome is that the uses of FPs would disappear from the EU. This is in principle highly negative under this factor because it would heavily impact key applications related to EU objectives like the Green Deal or the technological transition, among others. Yet, the removal of the FPs themselves could be seen as a positive outcome in that it would take away potential pollutants from the environment. For this reason, the score is assumed in a range -3/-2. However, by considering that regulatory actions on FPs will be coupled with the review and improvement of EU legislation dealing with treatment of waste, which will likely result in improvements in the minimisation of emissions of by-products generated during end-of-life of FPs, it could be reasonably concluded that the evaluation of the full restriction RMO under this factor would probably lean more towards -3 than -2, since the weight of the "favourable" consideration would be reduced by the impact of the RMO related to updates on EU waste legislation.

Uncertainties are unavoidable when developing an RMOA, and they need to be taken into account when evaluating the results. In the case of FPs, the margins established in the overall scores for the different RMOs, with minimum and maximum values derived from the assignment of individual scores to factors and application of weights as per the RMOA methodology, reflect those uncertainties. Tables 46 through 49 provide further description of the score ranges obtained per factor under each RMO, as well as overall RMO score ranges.

The minimum score obtained for the VII RMO (11.50) is clearly higher than the maximum score obtained for the full restriction RMO (-2.00) and also higher than the maximum possible score for the partial restriction RMO (7.50). Since there are no overlaps, this can be considered as a reinforcement on the conclusion that the VII (combined with updating relevant EU legislation to deal with end-of-life aspects) should be the preferred RMO to deal with potential concerns derived from the manufacture and use of FPs.

Table 46. Scoring of the RMO 1 Full Restriction.

Criteria	Factor	Score Range	Weighted Score Range
Effectiveness	Risk reduction capacity	+3	6.00
	Measurability / Monitorability	+3	3.75
	Timing to implementation	+3	3.75
Practicability	Implementability	-3	-3.00
	Enforceability	+2	2.00
	Manageability	-3	-3.00
Broader Impacts	Additional human health or environmental impacts	-3	-4.50
	Socio-economic impacts	-3/-2	-4.50/-3.00
Regulatory Consistency	Consistency with existing EU legislation	-2	-2.00
	Consistency with other EU policy objectives	-3/-2	-3.00/-2.00
		Overall RMO score range	**-4.50/-2.00**

Table 47. Scoring of the RMO 2 Partial Restriction.

Criteria	Factor	Score Range	Weighted Score Range
Effectiveness	Risk reduction capacity	+2/+3	4.00/6.00
	Measurability / Monitorability	+2/+3	2.50/3.75
	Timing to implementation	+3	3.75
Practicability	Implementability	-2	-2.00
	Enforceability	+1	1.00
	Manageability	-2	-2.00
Broader Impacts	Additional human health or environmental impacts	-3/-2	-4.50/-3.00
	Socio-economic impacts	-2	-3.00
Regulatory Consistency	Consistency with existing EU legislation	+2/+3	2.00/3.00
	Consistency with other EU policy objectives	-1/0	-1.00/0.00
		Overall RMO score range	**0.75/7.50**

Table 48. Scoring of the RMO 3 Voluntary Industry Initiative.

Criteria	Factor	Score Range	Weighted Score Range
Effectiveness	Risk reduction capacity	+2	4.00
	Measurability / Monitorability	+1	1.25
	Timing to implementation	+1/+2	1.25/2.50
Practicability	Implementability	-1/0	-1.00/0.00
	Enforceability	+1	1.00
	Manageability	+1	1.00
Broader Impacts	Additional human health or environmental impacts	0/+1	0.00/1.50
	Socio-economic impacts	0/+1	0.00/1.50
Regulatory Consistency	Consistency with existing EU legislation	+1	1.00
	Consistency with other EU policy objectives	+3	3.00
		Overall RMO score range	**11.50/16.75**

Table 49. Scoring of the RMO 4 Update of Existing EU Regulations on end-of-life.

Criteria	Factor	Score Range	Weighted Score Range
Effectiveness	Risk reduction capacity	+1/+2	2.00/4.00
	Measurability / Monitorability	+1	1.25
	Timing to implementation	+1	1.25
Practicability	Implementability	-1	-1.00
	Enforceability	+2/+3	2.00/3.00
	Manageability	+1	1.00
Broader Impacts	Additional human health or environmental impacts	0/+1	0.00/1.50
	Socio-economic impacts	0/+1	0.00/1.50
Regulatory Consistency	Consistency with existing EU legislation	+3	3.00
	Consistency with other EU policy objectives	+3	3.00
		Overall RMO score range	**12.50/18.50**

Finally, Table 50 summarises the minimum, maximum and average scores obtained for each RMO, along with calculated standard deviations and standard error values. These values are not intended to provide statistical significance to the scores and calculations performed, but to give an overview of the degree of uncertainty and variability when evaluating the expected outcome of each different RMO.

Table 50. Summary of scores, standard deviation, and error for each RMO

	Min. Score	Average Score	Max. Score	Std. Dev.	Std. Err.
RMO 1: Full restriction	-4.50	**-3.25**	-2.00	1.77	1.25
RMO 2: Restriction with derogations for FPs	0.75	**4.13**	7.50	4.77	3.38
RMO 3: VII following restriction with derogations for FPs and PFAS	11.50	**14.13**	16.75	3.71	2.63
RMO 4: Update of EU legislation on waste treatment	12.50	**15.50**	18.50	4.24	3.00

4. CONCLUSIONS

The initiative from 5 EEA Member States to propose a restriction under the REACH Regulation on PFAS that may impact fluoropolymers justifies the preparation of a Regulatory Management Option Analysis, in order to identify if the inclusion of these distinctively different set of materials in regulatory initiatives on PFAS is justified.

The review of existing information on fluoropolymers, including feedback received from surveys among manufacturers, importers and DUs has confirmed that fluoropolymers are critical materials for the progress of the European society as they provide multiple benefits in a wide array of very important sectors. There are practically no alternatives that can replace the high performance provided by fluoropolymers in virtually every critical application in which they are used. Continued availability of fluoropolymers is deemed necessary to achieve the internal goals that the EU has set on areas like decarbonization, renewable energies or competitiveness in the digital transition. On the other hand, while fluoropolymers are regarded as a differentiated category within the PFAS group, due to their very low toxicological profile and the fact that the most relevant fluoropolymers are regarded as polymers of low concern, it is confirmed that potential risks may be derived from the manufacture, use and end-of-life treatment of fluoropolymers, mainly due to the use of other PFAS in the manufacturing process, to potential presence of other chemicals bound to the commercial fluoropolymer products, or to decomposition into other chemicals at end-of-life stages that may generate concern for human health or the environment.

A Regulatory Management Option Analysis has been performed on fluoropolymers, following a predefined methodology, intended to identify the most appropriate instrument to address potential concerns. Such instrument should provide the best possible balance between risk control and enhancement of the competitiveness of the European industry. The outcome of the analysis shows that the inclusion of fluoropolymers in the REACH restriction of PFAS would not be an adequate regulatory option. Other possibilities exist that are expected to show better overall performance. This includes the combination of two options. First, the implementation of a Voluntary Industry Initiative of the fluoropolymer manufacturing industry, that will commit to introducing the best available techniques necessary to achieve specific objectives in terms of minimisation of exposure and emissions from hazardous chemicals related to the manufacture and use of fluoropolymers. These chemicals include residuals such as polymerisation aids, solvents, monomers, oligomers and/or unintended by-products from the manufacturing process. This should be agreed on the basis of granting derogations in the PFAS REACH restriction for the manufacture and uses of fluoropolymers, as well as for the use of PFAS required as polymerization aids or monomers in the manufacturing process. Second, the review of existing EU legislation in the field of waste treatment, that would enable setting emission levels of hazardous by-products generated during end-of-life treatment of fluoropolymers to acceptable levels.

The implementation of the Voluntary Industry Initiative will provide continuity to the already on-going efforts performed by fluoropolymer industry in ensuring responsible manufacturing practices, which are continuously leading to improvements for example in minimisation, and even removal of the use of PFAS from the manufacturing process of fluoropolymers as already engaged by some FP's manufacturers where technically possible. Continued R&D efforts and investment by industry are also leading to progress in the field of increasing recovery of PFAS used, or in the minimisation of hazardous side materials in the manufacturing process. This combination of regulatory measures should be coupled with enforcement actions to ensure that fluoropolymer products imported into the EU from non-EU manufacturers meet the same technical demands that will be imposed on fluoropolymers manufactured in the EU.

Since the economics of the fluoropolymer business are significantly intense, 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 non-profitable, which could result in the complete relocation of this industry outside the EU. This could have significant impacts for the whole fluoropolymer industry, with unpredictable consequences for the critical sectors that rely heavily on these materials.

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ANNEX I – Description of the Chemservice RMOA methodology

Introduction.

The purpose of a Regulatory Management Option Analysis (RMOA) is to help authorities clarify whether regulatory action is necessary for a given substance[1] having the potential to cause harm, and to identify the most appropriate measures to address a risk. By establishing a systematic, coherent, and transparent approach, the RMOA allows for an objective analysis of all the possible regulatory initiatives that could be undertaken on a given chemical. An RMOA can be developed by ECHA or by a Member State, however industry can also decide to carry out an Industry RMOA (i-RMOA).

Companies or industry sectors that take the initiative to prepare an i-RMOA may use its conclusions to anticipate and assist during regulatory reviews and challenges; it may also help industry to contribute credibly to the RMOAs developed by authorities, and to any subsequent decision processes at EU level.

An RMOA consists of different technical actions, that can be summarized as follows:

- Identification, discussion, and prioritization of risks related to a substance.
- Identification of all potential regulatory management options (RMOs) that could be proposed to eliminate, minimize, monitor, and control the probability and/or impact of the risks.
- Analysis of all the potential RMOs against a set of proportionality criteria and factors for their ability to reduce the risk.
- Identification of the most suited RMO or combination of RMOs.

While there is no official RMOA guidance or template established, different approaches have been used by authorities and industry to develop RMOAs in the context of the REACH and CLP Regulations. The present RMOA methodology has been developed using the following guidance documents as reference:

- ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007).
- Eurometaux Guidelines for an Industry Risk Management Option Analysis v3 (2017).
- ECHA Integrated Regulatory Strategy Report (2019).

Different criteria are evaluated in the RMOA; each criterion includes a set of independent yet related factors that help to frame the analysis, focusing on specific impacts that each one of the RMOs identified may trigger in relation to the specific factor under evaluation. The list of criteria and factors used in this RMOA methodology are described next:

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[1] An RMOA may be developed for a single substance, a group of substances or any other chemical linked to a specific potential concern.

Criteria and factors to be evaluated.

The different factors that will be analysed are grouped into 4 different criteria: Effectiveness, Practicability, Broader Impacts and Regulatory Consistency. The following indications aim at describing those criteria and factors, including a (non-exhaustive) list of questions that will be used to guide the developers through the RMO evaluation process.

- <u>Criterion 1. Effectiveness:</u> Degree to which the RMO is capable to produce the desired effect in terms of risk reduction, including possibility to measure effects. It is related to the efficacy of the RMO.
    - *Factor 1.1. Risk reduction capacity.*
        - Does the RMO reduce exposure to a level that allows adequate control of the identified risk?
    - *Factor 1.2. Measurability / monitorability.*
        - Can the necessary parameters required to evaluate or quantify the efficacy (amount of substance used, emission or exposure levels) of the RMO be easily identified and monitored?
    - *Factor 1.3. Time until implementation.*
        - What will be the expected time to implementation?
- <u>Criterion 2. Practicability:</u> Degree to which the RMO can be implemented, managed, and enforced. This is related to the efficiency of the RMO.
    - *Factor 2.1. Implementability.*
        - Can the involved actors understand, and implement the RMO easily?
        - Is it likely that the involved actors will be fully aware of implications in terms of obligations and responsibilities from implementation of the RMO?
        - Are the necessary techniques, technology, and alternatives available and economically feasible in the timeframe to implement the RMO?
    - *Factor 2.2. Enforceability.*
        - Will the authorities responsible for enforcement be able to verify compliance of relevant actors with the RMO?
        - Will the RMO allow the enforcement authorities to set up efficient supervision mechanisms?
    - *Factor 2.3. Manageability.*
        - Will the involved actors be capable of managing the progress of the RMO in terms of ensuring its effectiveness?
        - How complex are the supply chains that will be impacted, and will this influence the capacity to manage the RMO?
        - Is the administrative burden for actors concerned and authorities proportional to the risk to be avoided?

- Criterion 3. Broader Impacts: Degree to which the RMO brings balance between the expected effect (risk reduction) and any other impact on the supply chain and society. This will measure the potential effects that the RMO will have beyond the directly impacted stakeholders.
    - *Factor 3.1. Additional human health or environmental impacts.*
        - Is the use of the substance contributing to key applications to protect human health or the environment that would be put at risk by the implementation of the RMO?
    - *Factor 3.2. Socio-economic impacts.*
        - What impacts will the RMO bring at company and sectorial level, also on unsuspected value chains through product impacts (e.g., loss of functionality) and market impacts?
        - Are the efforts needed to implement the RMO and their impact adequately balanced with the adverse effects that are being avoided?
- Criterion 4. Regulatory consistency: Degree to which the RMO is in line with other EU existing or future initiatives, and how could implementation of the RMO impact those.
    - *Factor 4.1. Consistency with existing EU legislation.*
        - Is the RMO consistent with legal requirements already in place?
    - *Factor. 4.2. Consistency with other EU policy objectives.*
        - Would the implementation of the RMO lead to any unexpected impacts on other EU policy goals of the EU?

Scoring, weighting, and rating.

Each one of the factors listed above is analysed according to a scoring system, which is based on the expected positive or negative impact that the RMO may bring to each factor, compared with the baseline situation, or state of the art at the moment of conducting the RMOA. The scoring system used in this RMOA methodology is described next:

+3	High positive impact on the factor is expected from the implementation of the RMO
+2	Medium positive impact on the factor is expected from the implementation of the RMO
+1	Low positive impact on the factor is expected from the implementation of the RMO
0	Neutral impact on the factor is expected from the implementation of the RMO
-1	Low negative impact on the factor is expected from the implementation of the RMO
-2	Medium negative impact on the factor is expected from the implementation of the RMO
-3	High negative impact on the factor is expected from the implementation of the RMO

It is relevant to underline that not all the factors evaluated should be regarded as being of equal importance. For this reason, a weighting mechanism is introduced, that establishes specific weights for each relevant factor. In order to assign weights to factors, the general principle of any regulatory action at EU level, which is to ensure a high degree of protection of human health and the environment while enhancing the competitiveness of the EU industry, needs to be kept in mind. Taking this into consideration, the assumption is that factors within the 'Effectiveness' and 'Broader Impacts' criteria have to receive higher weights than those under 'Practicability' and 'Regulatory Consistency'. In a second step of the process to assign weights to factors, it is also considered that the 'Risk reduction capacity' should be the factor to receive the highest weight, which is set at twice the value of the baseline. Next, the two factors dealing with the 'Broader impacts' ('Additional human health or environmental impacts' and 'Socio-economic impacts') are assigned with a 50% stronger weight than the standard factors, in order to reflect the importance of the additional societal impacts that each RMO may bring. Finally, the remaining factors under 'Effectiveness' ('Measurability / Monitorability' and 'Expected time until implementation') are considered to be more important than the baseline factors, but of slightly lower relevance than the factors that have been previously discussed for the establishment of weights; therefore, they are assigned with a 25% increase compared to the baseline.

The following table gives an overview of the weights assigned to each factor, and their relevant contribution to the overall RMO scoring, based on the assumption of all factors being scored +1; the contribution of the criteria (which is a result of adding the individual contribution of each factor considered under each criteria) is also displayed.

Criteria	Factors	Weight Factor	Factor contribution	Criteria contribution
Effectiveness	Risk reduction capacity	2	16%	36%
	Measurability / monitorability	1.25	10%	
	Expected time until implementation	1.25	10%	
Practicability	Implementability	1	8%	24%
	Enforceability	1	8%	
	Manageability	1	8%	
Broader Impacts	Additional human health or environmental impacts	1.5	12%	24%
	Socio-economic impacts	1.5	12%	
Regulatory Consistency	Consistency with existing EU legislation	1	8%	16%
	Consistency with other EU policy objectives	1	8%	

In the final step, the scores for the different factors are added after application of the corresponding weight conversions, and the total scores for each one of the RMOs evaluated are compared. The RMO with the highest score should be selected as the most effective and proportionate regulatory route for the substance. In certain cases where different RMOs would be non-exclusive, or which would cover clearly differentiated stages of the life-cycle of a substance, combinations of RMOs could be selected.

With the result of the RMOA at hand, and as a final overview of the process, the following three questions to establish the overall proportionality of the RMO selected should be valuated:

a) Suitability: Is the RMO appropriate to achieve the objective that is pursued?

b) Necessity: Is there no other RMO considered suitable to achieve the objective that is less cumbersome, costly, or restrictive whilst equally effective in achieving the objective?

c) Proportionality *stricto sensu*: Is the RMO considered suitable and necessary, while not too excessive? Here, the balance between the different interests at stake (e.g., industry & society) need to be considered.

Data gathering and uncertainty.

Information used for developing the RMOA may come from many sources. In an i-RMOA, the sponsor industry (either a company or an association) should provide as much data as possible to the team in charge of building the RMOA. Moreover, information from regulatory sources (e.g., ECHA website) will be useful to adequately describe potential concerns for regulators. Ultimately, surveys established through the value chain should be put in place to collect as much information as possible, especially for evaluation of impacts downstream to the users of a substance. All these data sources will contribute to the uncertainty, which will have to be adequately considered in the RMOA.

The development of the RMOA, including scoring of the different factors, is subject to the interpretation of the developers and dependent on the accuracy and reliability of the data used for the analysis (it is not always possible for the developers to ensure that the data used is fully accurate, as this will frequently be provided by the sponsor of the RMOA or other interested parties). For this reason, the outcome of the RMOA will inevitably be subject to interpretation. In order to reflect this, it is possible for the developers to provide combined or non-fixed scores for a given factor (e.g., +1/+2), depending on the level of uncertainty. This needs to be adequately documented by the developers.

The use of non-fixed scores per factor will lead to variable overall scores, resulting in minimum, maximum and average values for the different RMOs. The use of weights, most of which are greater than one, will increase the variability. In principle, average values should be used for comparison, however the different ranges obtained for each RMO should be compared as well. Overlaps for different RMOs (e.g., the average of RMO1 is higher than the average of RMO2, but the maximum score of RMO2 is higher than the minimum score of

RMO1) need to be evaluated carefully. If these overlaps are significant, or if they may rise question on why one RMO should be preferred over another, then it may be concluded that the assessment is not robust enough, and further refinement of the data used for the evaluation could be required, for example, by improving the socio-economic impact evaluation of the different possible RMOs to be considered, to allow for a more accurate score to be assigned.

ANNEX II – Questionnaires for RMOA on Fluoropolymers

Questionnaire for Manufacturers

I. Company description

1. Please provide identification information of your company

Company Name	
Country	
Contact person name	
Role	
Telephone number	
e-mail address	

2. Please indicate the industry sector that you are representing. Use NACE nomenclature from:

   http://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Business_economy_by_sector_-_NACE_Rev._1.1

Industry sector	
NACE code	
Additional information	

3. Is your company considered an SME (Small and Medium-sized Enterprise) in the EEA[1]?

   YES / NO

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[1] EEA: European Economic Area = EU + Iceland, Liechtenstein, and Norway.

4. What is your position in the supply chain (Manufacturer, Distributor, Formulator, Downstream User (DU), Manufacturer of Articles (MoA), etc.)? Please select from the list below.

Manufacturer	**Distributor**	**Formulator**	**Downstream User (DU)**	**Manufacturer of Articles (MoA)**	**Other (please specify)**

5. How many of the sites that your company operates in the EEA are concerned?

Number of sites (please specify countries where sites are located)	

II. FPs of interest

6. Please indicate the FPs that are of interest to your company (add if necessary)[2]

Acronym	**Name**	**CAS #**	**Interested?**
ECTFE	copolymer of ethylene and chlorotrifluoroethylene	25101-45-5	
ETFE	ethylene tetrafluoroethylene	25038-71-5 / 68258-85-5	
FEP	fluorinated ethylene propylene	25067-11-2	
PFA	perfluoroalkoxy polymer	26655-00-5 / 31784-04-0	
PTFE	Polytetrafluoroethylene	9002-84-0	
PVDF	polyvinylidene fluoride	24937-79-9	
THV	terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride	25190-89-0	

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[2] This list of FPs is extracted from the Guide for the Safe Handling of Fluoropolymer Resins: https://www.plasticseurope.org/en/resources/publications/108-guide-safe-handling-fluoropolymer-resins

III. Manufacturing of FPs - Volumes

7. Please indicate volume of FPs manufactured in the past three years (expressed as tons per annum)

	2017	2018	2019
ECTFE			
ETFE			
FEP			
PFA			
PTFE			
PVDF			
THV			

8. Please indicate in what application / sector of use the relevant FP is sold.

	Aerospace	Architecture	Automotive	Chemicals	Power	Cookware	Electronics	Food	Pharma	Medical applications	Renewable energy	Textile
ECTFE												
ETFE												
FEP												
PFA												
PTFE												
PVDF												
THV												

Please describe the sector of use in case it was not listed above and add further details.

Sector of use	Explanation

9. Please indicate the approximate percentage (value or range) of volume of FP sold in each application / sector of use. Use column "Other" (and add new columns, if necessary) for sectors added in question 8.

	Aerospace	**Architecture**	**Automotive**	**Chemicals**	**Power**	**Cookware**	**Electronics**	**Food**	**Pharma**	**Medical applications**	**Renewable energy**	**Textile**	**Other**
ECTFE													
ETFE													
FEP													
PFA													
PTFE													
PVDF													
THV													

IV. Manufacturing of FPs – Exposure & Emissions

10. What type of polymerisation process are you using for the manufacturing of FPs (suspension, emulsion, etc.)? If different processes are used, please, specify the types and the FPs manufactured with each one.

11. Is your company using any PFAS as polymerization aids during the manufacturing of FPs? If yes, please, indicate which ones you are using, the FPs manufactured with each one, and the approximate percentage of use (value or range).

12. If you are using PFAS as polymerization aids, could they be removed from the manufacturing process? If so, what could be the available alternatives (no PFAS)[3]? Please, specify by type of FP manufactured with each possible alternative.

13. If you are using PFAS as polymerization aids, are you aware of the presence of free PFAS in the FPs after the manufacturing process? If yes, do you know in what proportion they are present? Please, specify by type of FP manufactured.

14. Are you aware of the presence of free monomers and/or oligomers in the FPs due to an incomplete polymerisation process? If yes, do you know in what proportion they are present? Please, specify by type of FP manufactured.

15. Does your company perform regular occupational exposure monitoring on-site for the manufacturing of FPs? If yes, does this monitoring include determination of the PFAS used as polymerization aids (if any)? Could the results of monitoring campaigns be made available for the purpose of improving the RMOA[4]?

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[3] Substitution of PFAS polymerization aids by other PFAS cannot be considered an alternative in this case.

[4] It is assumed that relevant CSRs will be made available for the preparation of the RMOA.

16. In your opinion, is there room for improvement to control exposure at the workplace for the manufacturing of FPs or the use of PFAS (if any), e.g., via implementation of additional Risk Management Measures or improvement of Operating Conditions? If yes, please, provide details.

17. Does your company perform regular monitoring on-site to control emissions to the environment during the manufacturing of FPs? If yes, does this monitoring include determination of the PFAS used as polymerization aids (if any)?

18. In your opinion, is there room for improvement to control emissions to the environment during the manufacturing of FPs or the use of PFAS (if any)? If yes, please, provide details.

19. Does your manufacturing permit include any obligation related to control emissions to the environment during the manufacturing of FPs or the use of PFAS (if any)? If yes, please, provide details about these obligations.

20. Are limits defined in your country for emissions to the environment of any kind of FPs/PFAS? If so, which are these limits?

21. Please indicate the number of employees potentially exposed during the manufacturing of FPs at your company over the last three years, per EEA country of relevance

EEA Country	**2017**	**2018**	**2019**

V. Manufacturing of FPs – Disposal and end of life information

22. What is the treatment of the waste generated during the manufacturing of FPs (recycling, energy recovery by incineration, landfill, etc.)? If different treatments are applied, please, specify the waste involved in each one and the proportion regarding the total waste.

23. Do you have information regarding the waste treatment of the products the supply chain is manufacturing with your FPs (recycling, energy recovery by incineration, landfill, etc.)? If yes, please, provide details.

24. Is it possible to establish approximate percentages of waste treatments for the products of the supply chain? Also, if possible, establish percentages per application / sector of use (SU). Add columns if necessary.

Waste treatment	**% (Total)**	**% (SU1)**	**% (SU2)**	**% (SU3)**
Recycling				
Energy recovery (incineration)				
Landfill				

25. If the end of life of the products of the supply chain is recycling, do you have information regarding the fate of the FPs contained in them (application, sector of use, etc.)? If yes, please, provide details.

VI. Manufacturing of FPs – Economic information

26. Please indicate profit[5] generated from FPs manufactured by your company in the EEA in the past years (please specify units in which data is provided, e.g., k€, m€).

	2017	**2018**	**2019**
ECTFE			
ETFE			
FEP			
PFA			
PTFE			
PVDF			
THV			

27. If possible, please, provide approximate percentages of global business linked to the FPs manufactured (i.e., ratio between answer to question 26 and total profit from the company in the EEA)?

	2017	**2018**	**2019**
ECTFE			
ETFE			
FEP			
PFA			
PTFE			
PVDF			
THV			

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[5] Various options can be used as a measure for “profit” (e.g., EBITDA, net / gross profit margin… Please be sure to specify which one you are using.

28. In the past years (2017-2019), what has been your EEA market share related to the specific sectors described in question 9? Please provide an estimate. Add a table for each of the year.

Year:	**Aerospace**	**Architecture**	**Automotive**	**Chemicals**	**Power**	**Cookware**	**Electronics**	**Food**	**Pharma**	**Medical applications**	**Renewable energy**	**Textile**	**Other**
ECTFE													
ETFE													
FEP													
PFA													
PTFE													
PVDF													
THV													

VII. Criticality of the FPs

29. How would you describe the importance of each FP for your business?

	Extremely Important	**Important**	**Not very important**	**Do not know**
ECTFE				
ETFE				
FEP				
PFA				
PTFE				
PVDF				
THV				

If you have answered “extremely important” or “important”, could you please provide further details if possible, in terms of why the FP is critical for your business?

The FP is extremely important / important because…

30. If the FP of interest were to be included in the restriction proposal for PFAS, what do you think would be the consequence for / reaction from your company, from the following options? **Please note** - It is possible that different options could be selected for the same FP depending on the uses.

a) Manufacturing / marketing of an alternative (more questions on alternatives on section VIII)

b) Cease of business linked to the FP

c) Relocation: What would be the estimated associated cost, in terms of e.g., training of workers, building of new facility outside the EEA, transfer of knowledge, etc.?

d) Continue business under the conditions imposed by the restriction proposal

	Manufacturing / marketing of alternative	**Business termination in EEA**	**Business reallocation outside EEA**	**Continuation of business under restriction conditions**
ECTFE				
ETFE				
FEP				
PFA				
PTFE				
PVDF				
THV				

31. If possible, could you please estimate the % of your profit linked to the FP for each option and the global profit that could be impacted?

	Use of alternative	**Business termination in EEA**	**Business reallocation outside EEA**	**Continuation of business under restriction conditions**
% of profit generated by the FP in the EEA for each option				
% of global profit that could be impacted (knock on effect)				

32. If the FPs were to be banned for the relevant use(s) in the EEA, and if this would lead your company to terminate or reallocate your business (i.e., no alternative chemical available), please provide further details to your position.

Justification why business would be terminated / relocated

33. Do you know is some of the relevant use(s) of the FPs in the EEA could be considered "essential use(s)"?

VIII. Manufacturing / marketing of alternatives

According to ECHA Guidance, alternatives have to be technically and economically feasible, provide equivalent performance, be available in sufficient quantity for industry, and they have to result in overall reduced risk compared to the chemical of concern. Alternatives may involve replacement of a chemical by another chemical, or by a combination of chemicals, or by switching to different technologies.

34. Please describe the technical function of the FP, and the performance expected from the use of the FP in the supply chain, per type of use (add boxes as needed – alternatively, references to literature on the topic can be provided).

Type of Use / FP	**Technical function**	**Expected performance**
Use 1 (please specify)		
Use 2 (please specify)		

35. Please indicate how you evaluate potential alternatives[6] to the FPs for your industry in the table below. If possible, please, add a rough estimate of the cost related to the replacement of FPs by each alternative.

a) Evaluate technical and economic feasibility, and fitness for use (e.g., same function & level of performance; if not the same, explain the difference).
b) Specify the type of use for each alternative if the FP has different uses.
c) Do you know if these alternatives have hazardous properties for human health and/or the environment? Are they regulated equally to the FP, or is it reasonably expected that they will be in the future?
d) What is the timeline of the possible implementation of the alternative(s)? Do you have any information to justify your estimated timeline for the implementation of the alternative(s)?

Alternative	**General assessment of the alternative**
Alternative 1 (please specify)	
Alternative 2 (please specify)	
Alternative 3 (please specify)	

36. Would your customers accept a reduction in product performance? At what cost?

Please justify your answer

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[6] Substitution of FPs by other FPs or PFAS cannot be considered an alternative in this case.

IX. Expected impact of Regulatory Management Options

37. Based on your knowledge of the supply chain, who do you think will be the most impacted in the supply chain in case of a REACH restriction?

Manufacturer	Formulator	Downstream User (DU)	Manufacturer of Articles (MoA)	Other (please specify)

38. If the REACH restriction would force you to terminate and/or reallocate your business, please explain why.

Please justify your answer

39. Please indicate a rough estimate of compliance costs[7] of the REACH restriction (if you operate several sites, please specify if your answer refers to the cost implementation for one site or for all together)

Please justify your answer

40. Please explain why (if at all) your cost would increase under the considered REACH restriction.

Please justify your answer

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[7] Compliance costs include all the expenses that a company incurs to adhere to industry Regulations (e.g., salaries of people working in compliance, time and money spent on reporting, regulatory fees and taxes, new systems required to meet retention, etc.)

41. Do you know if the Risk Management Measures (RMM) in place at your facility(ies) are in line with industry standards, e.g., Best Available Techniques (BAT)? If not, do you know the cost that would be required to update your RMM at the BAT level or equivalent?

Please justify your answer

42. What would be the timeline to implement the update of Risk Management Measures?

Please justify your answer

43. Whatever the regulatory option, what would be the maximum cost that you would be willing to undertake to implement extra risk management measures (to limit the release), to have the right to continue manufacturing FPs: 100, 250, 500, 1000 k€, or other (please give an approximation)

Please justify your answer

44. How many jobs do you think that you company would be forced to terminate in the EEA in each considered scenario (REACH restriction, termination and/or reallocation of the business, implementation of BAT)? Please specify type of jobs that would be lost, and EEA country of relevance.

Please justify your answer

X. Other effects

Please indicate any other information of concern, or that you consider relevant for the socio- economic analysis of FPs.

Questionnaire for Downstream Users (DU)

I. Company description

1. Please provide identification information of your company

Company Name	
Country	
Contact person name	
Role	
Telephone number	
e-mail address	

2. Please indicate the industry sector that you are representing. Use NACE nomenclature from:

   http://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Business_economy_by_sector_-_NACE_Rev._1.1

Industry sector	
NACE code	
Additional information	

3. Is your company considered an SME (Small and Medium-sized Enterprise) in the EEA[1]?

   YES / NO

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[1] EEA: European Economic Area = EU + Iceland, Liechtenstein, and Norway.

4. What is your position in the supply chain (Manufacturer, Distributor, Formulator, Downstream User (DU), Manufacturer of Articles (MoA), etc.)? Please select from the list below.

Manufacturer	**Distributor**	**Formulator**	**Downstream User (DU)**	**Manufacturer of Articles (MoA)**	**Other (please specify)**

5. How many of the sites that your company operates in the EEA are concerned?

Number of sites (please specify countries where sites are located)	

II. FPs of interest

6. Please indicate the FPs that are of interest to your company (add if necessary)[2]

Acronym	**Name**	**CAS #**	**Interested?**
ECTFE	copolymer of ethylene and chlorotrifluoroethylene	25101-45-5	
ETFE	ethylene tetrafluoroethylene	25038-71-5 / 68258-85-5	
FEP	fluorinated ethylene propylene	25067-11-2	
PFA	perfluoroalkoxy polymer	26655-00-5 / 31784-04-0	
PTFE	polytetrafluoroethylene	9002-84-0	
PVDF	polyvinylidene fluoride	24937-79-9	
THV	terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride	25190-89-0	

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[2] This list of FPs is extracted from the Guide for the Safe Handling of Fluoropolymer Resins: https://www.plasticseurope.org/en/resources/publications/108-guide-safe-handling-fluoropolymer-resins

III. Use of FPs - Volumes

7. Please indicate volume of FPs used in the past three years (expressed as tons per annum)

	2017	2018	2019
ECTFE			
ETFE			
FEP			
PFA			
PTFE			
PVDF			
THV			

8. Please indicate in what application / sector of use the relevant FP is used.

	Aerospace	Architecture	Automotive	Chemicals	Power	Cookware	Electronics	Food	Pharma	Medical applications	Renewable energy	Textile
ECTFE												
ETFE												
FEP												
PFA												
PTFE												
PVDF												
THV												

Please describe the sector of use in case it was not listed above and add further details.

Sector of use	Explanation

9. Please indicate the approximate percentage (value or range) of volume of FP used in each application / sector of use. Use column “Other” (and add new columns, if necessary) for sectors added in question 8.

	Aerospace	**Architecture**	**Automotive**	**Chemicals**	**Power**	**Cookware**	**Electronics**	**Food**	**Pharma**	**Medical applications**	**Renewable energy**	**Textile**	**Other**
ECTFE													
ETFE													
FEP													
PFA													
PTFE													
PVDF													
THV													

IV. Use of FPs – Exposure & Emissions

10. Is your company using any PFAS as polymerization aids during the manufacturing process of your products involving FPs? If yes, please, indicate which ones you are using and the approximate percentage of use (value or range).

11. Have you detected the presence of free PFAS (if used as polymerization aids), monomers and/or oligomers in the FPs you are using? If yes, do you know in what proportion they are present? Please, specify by type of FP involved.

12. Does your company perform regular occupational exposure monitoring on-site for processes involving FPs? If yes, could the results of monitoring campaigns be made available for the purpose of improving the RMOA[3]?

13. In your opinion, is there room for improvement to control exposure at the workplace for processes involving FPs, e.g., via implementation of additional Risk Management Measures or improvement of Operating Conditions? If yes, please, provide details.

14. Does your company perform regular monitoring on-site to control emissions to the environment during the manufacturing process of your products involving FPs? If yes, please, provide details.

15. In your opinion, is there room for improvement to control emissions to the environment during the manufacturing process with FPs? If yes, please, provide details.

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[3] It is assumed that relevant CSRs will be made available for the preparation of the RMOA.

16. Please indicate the number of employees potentially exposed during the manufacturing process of your products involving FPs at your company over the last three years, per EEA country of relevance.

EEA Country	2017	2018	2019

V. Use of FPs – Disposal and end of life information.

17. Do you have information regarding the waste treatment of the products that you are manufacturing with FPs (recycling, energy recovery by incineration, landfill, etc.)? If yes, please, provide details.

18. Is it possible to establish approximate percentages of waste treatments for your products? Also, if possible, establish percentages per application / sector of use (SU). Add columns if necessary.

Waste treatment	% (Total)	% (SU1)	% (SU2)	% (SU3)
Recycling				
Energy recovery (incineration)				
Landfill				

19. If the end of life of your products is recycling, do you have information regarding the fate of the FPs contained in them (application, sector of use, etc.)?

VI. Use of FPs – Economic information

20. Please indicate profit[4] generated from products produced by your company in the EEA in the past years (please specify units in which data is provided, e.g., k€, m€).

	2017	**2018**	**2019**
ECTFE			
ETFE			
FEP			
PFA			
PTFE			
PVDF			
THV			

---

[4] Various options can be used as a measure for “profit” (e.g., EBITDA, net / gross profit margin… Please be sure to specify which one you are using.

21. If possible, please, provide approximate percentages of global business linked to the FPs manufactured (i.e., ratio between answer to question 22 and total profit from the company in the EEA)?

	2017	**2018**	**2019**
ECTFE			
ETFE			
FEP			
PFA			
PTFE			
PVDF			
THV			

22. In the past years (2017-2019), what has been your EEA market share related to the specific sectors described in question 9? Please provide an estimate. Add a table for each of the year.

Year:	**Aerospace**	**Architecture**	**Automotive**	**Chemicals**	**Power**	**Cookware**	**Electronics**	**Food**	**Pharma**	**Medical applications**	**Renewable energy**	**Textile**	**Other**
ECTFE													
ETFE													
FEP													
PFA													
PTFE													
PVDF													
THV													

VII. Criticality of the FPs

23. How would you describe the importance of each FP for your business?

	Extremely Important	**Important**	**Not very important**	**Do not know**
ECTFE				
ETFE				
FEP				
PFA				
PTFE				
PVDF				
THV				

If you have answered “extremely important” or “important”, could you please provide further details if possible, in terms of why the FP is critical for your business?

The FP is extremely important / important because…

24. If the FP of interest were to be included in the restriction proposal for PFAS, what do you think would be the consequence for / reaction from your company, from the following options? **Please note** - It is possible that different options could be selected for the same FP depending on the uses.

e) Manufacturing / marketing of an alternative (more questions on alternatives on section VIII)

f) Cease of business linked to the FP

g) Relocation: What would be the estimated associated cost, in terms of e.g., training of workers, building of new facility outside the EEA, transfer of knowledge, etc.?

h) Continue business under the conditions imposed by the restriction proposal

	Manufacturing / marketing of alternative	Business termination in EEA	Business reallocation outside EEA	Continuation of business under restriction conditions
ECTFE				
ETFE				
FEP				
PFA				
PTFE				
PVDF				
THV				

25. If possible, could you please estimate the % of your profit linked to the FP for each option and the global profit that could be impacted?

	Use of alternative	Business termination in EEA	Business reallocation outside EEA	Continuation of business under restriction conditions
% of profit generated by the FP in the EEA for each option				
% of global profit that could be impacted (knock on effect)				

26. If the FPs were to be banned for the relevant use(s) in the EEA, and if this would lead your company to terminate or reallocate your business (i.e., no alternative chemical available), please provide further details to your position.

Justification why business would be terminated / relocated

VIII. Manufacturing / marketing of alternatives

According to ECHA Guidance, alternatives have to be technically and economically feasible, provide equivalent performance, be available in sufficient quantity for industry, and they have to result in overall reduced risk compared to the chemical of concern. Alternatives may involve replacement of a chemical by another chemical, or by a combination of chemicals, or by switching to different technologies.

27. Please describe the technical function of the FP, and the performance expected from the use of the FP in the supply chain, per type of use (add boxes as needed – alternatively, references to literature on the topic can be provided).

Type of Use / FP	Technical function	Expected performance
Use 1 (please specify)		
Use 2 (please specify)		

28. Please indicate how you evaluate potential alternatives[5] to the FPs for your industry in the table below. If possible, please, add a rough estimate of the cost related to the replacement of FPs by each alternative.

e) Evaluate technical and economic feasibility, and fitness for use (e.g., same function & level of performance; if not the same, explain the difference).

f) Specify the type of use for each alternative if the FP has different uses.

g) Do you know if these alternatives have hazardous properties for human health and/or the environment? Are they regulated equally to the FP, or is it reasonably expected that they will be in the future?

h) What is the timeline of the possible implementation of the alternative(s)? Do you have any information to justify your estimated timeline for the implementation of the alternative(s)?

Alternative	General assessment of the alternative
Alternative 1 (please specify)	
Alternative 2 (please specify)	
Alternative 3 (please specify)	

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[5] Substitution of FPs by other FPs or PFAS cannot be considered an alternative in this case.

29. Would your customers accept a reduction in product performance? At what cost?

Please justify your answer

IX. Expected impact of Regulatory Management Options

30. Based on your knowledge of the supply chain, who do you think will be the most impacted in the supply chain in case of a REACH restriction?

Manufacturer	**Formulator**	**Downstream User (DU)**	**Manufacturer of Articles (MoA)**	**Other (please specify)**

31. If the REACH restriction would force you to terminate and/or reallocate your business, please explain why.

Please justify your answer

32. Please indicate a rough estimate of compliance costs[6] of the REACH restriction (if you operate several sites, please specify if your answer refers to the cost implementation for one site or for all together)

Please justify your answer

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[6] Compliance costs include all the expenses that a company incurs to adhere to industry Regulations (e.g., salaries of people working in compliance, time and money spent on reporting, regulatory fees and taxes, new systems required to meet retention, etc.)

33. Please explain why (if at all) your cost would increase under the considered REACH restriction.

Please justify your answer

34. Do you know if the Risk Management Measures (RMM) in place at your facility(ies) are in line with industry standards, e.g., Best Available Techniques (BAT)? If not, do you know the cost that would be required to update your RMM at the BAT level or equivalent?

Please justify your answer

35. What would be the timeline to implement the update of Risk Management Measures?

Please justify your answer

36. Whatever the regulatory option, what would be the maximum cost that you would be willing to undertake to implement extra risk management measures (to limit the release), to have the right to continue manufacturing FPs: 100, 250, 500, 1000 k€, or other (please give an approximation)

Please justify your answer

37. How many jobs do you think that you company would be forced to terminate in the EEA in each considered scenario (REACH restriction, termination and/or reallocation of the business, implementation of BAT)? Please specify type of jobs that would be lost, and EEA country of relevance.

Please justify your answer

X. Other effects

Please indicate any other information of concern, or that you consider relevant for the socio- economic analysis of FPs.

ANNEX III – Summary of replies to the RMOA questionnaires

For the purpose of this RMOA, two surveys were conducted with the intention to collect updated information related to the manufacture and use of FPs in the EU; one survey was conducted between the members of the FPG, which are manufacturers, importers of FPs[1] in the EU[2], and a second one was performed between DUs in the supply chain of FPs.

All the members of the FPG replied to the questionnaires that were delivered for this purpose. While information on socio-economic value of FPs was requested, the objective of the questionnaires distributed to the manufacturers and importers was more focused on technical aspects related to safety, exposure, and manufacturing conditions of FPs.

A total of 7 companies participated in the survey for manufacturers, which include all the FPG members at the time of initiating the RMOA. 16 sites in the EU were identified by these companies as being involved in the handling of FPs, with 9 of those being directly involved in the manufacturing of FPs, at the following locations: France (3), Germany (2), The Netherlands (2), Italy (1) and Belgium (1). The remaining 7 sites in the EU operated by FPG members formulate or process FPs in one way or another, and are located in Germany (3), Italy (3) and the Netherlands (1). One FPG member manufactures FPs in the UK.

All of these companies operate occupational health, safety, and environmental management systems in compliance with (or based on) international standards (ISO 45001, OHSAS 18001, ISO 14001, RC 14001), which include the regular performance of occupational and environmental exposure monitoring, and training programs for the workers. In this regard, all the companies reported their believe that there is room for continuous improvement to control both exposure at the workplace and emissions to the environment.

All of the members of FPG are large companies (i.e., no SMEs involved). In terms or reported criticality for their business, all the manufacturers reported that the FPs they produce are important or very important (all the manufacturers reported at least one FP as being very important), and they also agreed on the fact that their customers would not in general accept a reduction in performance. The fact that FPs are a high-cost solution which are used as the material of choice when absolutely necessary was frequently reported. Ultimately unjustified regulatory pressure on FPs may force them to re-evaluate their position in terms of manufacturing FPs in the EU.

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[1] Some of the FPG members also play the role of downstream users as they perform further polymerization of FPs at dedicated facilities.

[2] Some members of the FPG are in the UK, therefore they were formally impacted by EU Regulations as manufacturers when this RMOA was initiated.

Table A.III 1. Sectors of use reported by respondents (more than one selection is possible)

Chemicals and/or petrochemicals	4	44.45%
Plastics production	3	33.33%
Rubber production; rubber compounder	2	22.22%
TOTAL	**9**	

Table A.III 2. List of FPs reported.

Abbreviation	Name	CAS #	Interested?
ECTFE	copolymer of ethylene and chlorotrifluoroethylene	25101-45-5	2
ETFE	ethylene tetrafluoroethylene	25038-71-5 / 68258-85-5	5
FEP	fluorinated ethylene propylene	25067-11-2	5
PFA	perfluoroalkoxy polymer	26655-00-5 / 31784-04-0	6
PTFE	polytetrafluoroethylene	9002-84-0	6
PVDF	polyvinylidene fluoride	24937-79-9	5
THV	terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride	25190-89-0	3
VDF/HFP - FKM	Vinylidene fluoride-hexafluoropropylene copolymer	9011-17-0	4
	Others (13 products)		15

Table A.III 3. Number of sites reported per country[3].

Germany	5	29.41%
Italy	4	23.53%
France	3	17.65%
Netherlands	3	17.65%
Belgium	1	5.88%
UK	1	5.88%
TOTAL	**17**	

Table A.III 4. Volume of FP produced in the past three years (expressed as tons per annum).

	2017	**2018**	**2019**
Overall	>43,000	>44,000	>40,000

Table A.III 5. Is your company using any PFAS as polymerization aids during the manufacturing process?

YES (some PFAS are used)	4	54.14%
YES/NO (depending on products)	2	28.57%
NO	1	14.29%
NA (No Answer)	0	0.00%
TOTAL	**7**	

Table A.III 6. Have you detected the presence of free PFAS (if used as polymerization aids) in the FPs you are producing?

YES (but always below limits)	6	85.71%
NO	1	14.29%
NA	0	0.00%
TOTAL	**7**	

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[3] Although the focus of the questionnaire was placed on companies based in the EEA, 1 reply was received from a company based in the UK. This company did report having EEA based offices. However, they were keen to provide replies on the claim that the EEA market is of very high importance for their business. Table A.III 3 shows the locations of sites reported in the survey (more than one site was reported by some respondents).

Table A.III 7. Have you detected the presence of free monomers and/or oligomers in the FPs you are producing?

YES (but always below limits)	6	85.71%
NO	0	0.00%
NA	1	14.29%
TOTAL	**7**	

In the case of DUs, a total of 46 replies were received to the questionnaires that were delivered throughout the supply chain. The questionnaires were delivered by the FPG secretariat and by the FPG members. Direct customers, but also industry associations were contacted and asked to provide replies to the questionnaires. It is estimated that around 400 contacts were established for this purpose, however this may be missing further distribution of the questionnaire in the supply chain, but it also may include double counting.

Out of the 46 replies, 2 were regarded as being of insufficient quality to take them into consideration for further analysis. The 44 replies analysed included representatives from a wide variety of sectors, and 2 of those replies came from industry associations, the rest being from individual companies.

Table A.III 8. Sectors of use reported by respondents (more than one selection is possible)

Plastics production	12	25.00%
Coatings	10	20.83%
Rubber production; rubber compounder	9	18.75%
Automotive, aerospace, engine	5	10.42%
Electronics /Technology / wire production	3	6.25%
Cookware	2	4.17%
Textile / leather	2	4.17%
Chemicals and/or fuel polymerization	3	6.25%
Water Treatment	1	2.08%
Lubricants	1	2.08%
TOTAL	**48**	

Table A.III 9. Number of sites reported per country[4].

Germany	23	26.74%
Italy	13	15.12%
UK	8	9.30%
France	6	6.98%
Spain	6	6.98%
Austria	4	4.65%
Poland	4	4.65%
Netherlands	4	4.65%
Hungary	3	3.49%
Sweden	3	3.49%
Belgium	3	3.49%
Czech Republic	2	2.33%
Ireland	2	2.33%
Portugal	2	2.33%
Romania	1	1.16%
Serbia	1	1.16%
Switzerland	1	1.16%
TOTAL	**86**	

Table A.III 10. Number of companies that identify themselves as SME (replies from Industry Associations not considered under NA).

YES	15	35.71%
NO	25	59.52%
NA	2	4.76%
TOTAL	**42**	

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[4] Although the focus of the questionnaire was placed on companies based in the EEA, 5 replies were received from companies based in the US, 2 replies came from UK-based companies, and 1 reply was received from a company based in Switzerland. Some of these did report having EEA based offices or sites. However, they were keen to provide replies on the claim that the EEA market is of very high importance for their business. Table xxx shows the locations of sites reported in the survey (not all companies provided information on number of sites, and more than one site was reported by many respondents).

Table A.III 11. List of FPs reported.

Abbreviation	Name	CAS #	Interested?
ECTFE	copolymer of ethylene and chlorotrifluoroethylene	25101-45-5	6
ETFE	ethylene tetrafluoroethylene	25038-71-5 / 68258-85-5	10
FEP	fluorinated ethylene propylene	25067-11-2	17
PFA	perfluoroalkoxy polymer	26655-00-5 / 31784-04-0	25
PTFE	polytetrafluoroethylene	9002-84-0	36
PVDF	polyvinylidene fluoride	24937-79-9	16
THV	terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride	25190-89-0	10
VDF/HFP - FKM	Vinylidene fluoride-hexafluoropropylene copolymer	9011-17-0	11
	Others (22 products)		28

Table A.III 12. Volume of FP used in the past three years (expressed as tons per annum).

	2017	2018	2019
Overall	>8,000	>9,000	>11,000

Table A.III 13. Is your company using any PFAS as polymerization aids during the manufacturing process?

Use of FPs as polymerization aids	3	6.82%
YES (some PFAS are used)	4	9.09%
NO	30	68.18%
NA (No Answer)	7	15.91%
TOTAL	**44**	

Table A.III 14. Have you detected the presence of free PFAS (if used as polymerization aids), monomers and/or oligomers in the FPs you are using?

YES (but always below limits)	7	15.91%
NO	25	56.82%
NA	12	27.27%
TOTAL	**44**	

Table A.III 15. Does your company perform regular occupational exposure monitoring on-site for processes involving FPs?

YES	15	34.09%
NO	22	50.00%
NA	7	15.91%
TOTAL	**44**	

Table A.III 16. In your opinion, is there room for improvement to control exposure at the workplace for processes involving FPs?

YES	9	20.45%
NO	22	50.00%
NA	13	29.55%
TOTAL	**44**	

Table A.III 17. Does your company perform regular monitoring on-site to control emissions to the environment during the manufacturing process of your products involving FPs?

YES	16	36.36%
NO	20	45.45%
NA	8	18.18%
TOTAL	**44**	

Table A.III 18. In your opinion, is there room for improvement to control emissions to the environment during the manufacturing process with FPs?

YES	7	15.91%
NO	22	50.00%
NA	15	34.09%
TOTAL	**44**	

Table A.III 19. Number of employees potentially exposed during the manufacturing process of products involving FPs.

Germany	618
Italy	161
Sweden	100
France	74
Ireland	65
Poland	65
Hungary	50
Belgium	50
Spain	15
TOTAL	1198

Table A.III 20. How would you describe the importance of the FP for your business?

FPs indicated as not very important	1	2.27%
Some FPs ranked very important; others not important	3	6.82%
FPs listed as important but there may be alternatives	1	2.27%
At least one FP listed as extremely important	39	88.64%
At least one FP listed as extremely important or very important	43	97.73%

Table A.III 21. Would customers accept a reduction in product performance?

YES	2	4.55%
NO	31	70.45%
NA	11	25.00%
TOTAL	**44**	

ANNEX IV – FPG Members' Responsible Manufacturing Commitment

PlasticsEurope
Association of Plastics Manufacturers
Fluoropolymers Product Group

FPG Members' Responsible Manufacturing Commitment and principles

As an industry, the fluoropolymer manufacturers have developed and implemented innovative solutions to minimize the environmental footprint related to fluoropolymer production and to reduce their potential emissions based on the best available techniques. The fluoropolymer industry has adopted and will continue to adopt and 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:

1. To maintain, continuously improve and/or develop best available techniques in the manufacturing processes and management of environmental emissions related to fluoropolymers.

2. To maintain and continuously improve and develop containment, capture, and recycle technologies to minimize emissions into the environment from PFAS substances intentionally and non-intentionally present in fluoropolymers including fluorinated raw materials, polymerization aids, monomers, intermediates, and process chemicals as well as by-products.

3. To continue investigating and developing R&D programs for the advancement of technologies allowing 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, to replace the use of PFAS as polymerization aids.

4. To continue to pro-actively 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. To continue to minimize the exposure levels for workers to chemicals used in the fluoropolymers manufacturing process.

6. To introduce new or expand existing third-party assessment programs to help verify progress towards our members' commitments.

7. To commit to an open dialogue with policymakers, employees, and other key stakeholders.

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.

As a first step, the Fluoropolymer Products Group is currently working on a review of wastewater related monitoring activities. The objective will be identification of best-practices and possibly recommendations for process changes.

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