ASSESSMENT

Of the impacts of a potential restriction of per-and polyfluoroalkyl substances (PFAS) on the tyre & rubber industry

SUBSTANCE: **Per- and polyfluoroalkyl substances (PFAS)**

FROM: **European Tyre & Rubber Manufacturers Association (ETRMA)**

USE: **in general rubber goods and the tyre manufacturing process**

DATE: **22 September 2023**

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This position and consultation response is a majority opinion and not all ETRMA Members agree. Consequently, those Members are not bound by this position.

Abbreviations

BPA	Bisphenol A
BPAF	Bisphenol AF
CAR	Competent Authority Report
DU	Downstream users
EBIT	Earnings Before Interest and Taxes
ECHA	European Chemicals Agency
EEA	European Economic Area
ETFE	Ethylene-tetrafluoroethylene copolymer
EU	European Union
EUR	Euro (currency)
FP	Fluoropolymers
FTE	Full Time Employee
FFKM	Perfluorine Kautschuk Material (perfluorelastomer materials)
IP	Intellectual Property
NPV	Net Present Value
OECD	Organization for Economic Co-operation and Development
PFAS	Per- and Polyfluoroalkyl Substances
PMT	Persistent, Mobile, and Toxic
PTFE	Polytetrafluoroethylene
RAC	Risk Assessment Committee
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SVHC	Substance of Very High Concern
TFM	Modified Tetrafluoroethylene
VPvM	Very Persistent and Very Mobile

Contents

Executive Summary

This Impact Assessment report focuses on fluoropolymers used in rubber goods applications and the tyre manufacturing process. It has been prepared by EPPA[1] at the request of European Tyre & Rubber Manufacturers Association (ETRMA) with the intention of providing EU regulators with evidence-based findings on the social and economic impacts that are expected to occur should this group of substances be restricted under REACH.

The assessment has been conducted in accordance with the existing official guidance from ECHA under REACH,[2] and it is based on information and data gathered from major tyre and rubber goods manufacturers members of ETRMA. The assessment is, therefore, highly representative and can serve as a basis for defining the anticipated socio-economic impacts resulting from a restriction of PFAS chemicals.

This report is a **continuation of ETRMA's first contribution** to the July 2021 call for evidence. The purpose of this contribution is to establish the scale and impact of a PFAS restriction on the tyre and General Rubber Goods (GRG) sectors. Due to the complexity of the definition and broad restriction, scope, ETRMA members are still assessing the presence of PFAS and **evaluating** the impacts on the tyre and GRG sector. Therefore, the data presented and estimates are very conservative. **ETRMA will submit a more detailed analysis during the next ECHA consultation.**

Main findings

- ***Properties and uses:***
  - **ETRMA members use mainly fluoropolymers, alongside BPAF as a cross-linking agent, which are part of the PFAS substance family, to produce rubber goods.**
    - For the General Rubber Goods (GRG) sector, **fluoropolymers, and in particular fluoroelastomers, are used in the manufacturing process of rubber articles.** They are also used in the machinery and equipment required for the manufacturing of rubber articles.
    - For the production of tyres, fluoropolymers are not used as raw materials nor components, but **FPs are only used in the functioning of some machinery and equipment** during the production of tyres.
  - **Fluoropolymers meet unique properties such as being virtually chemically inert, non-wetting, non-sticking, and highly resistant to temperature and wear** (with low migration values).

[1] www.eppa.com

[2] The ECHA Guideline for an SEA to be used in REACH Application for Authorisation is available at: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e

  - Fluoropolymers used by the rubber industry, such as FKM or PTFE are chemically, thermally and biologically stable; they do not present significant toxicological concerns and cannot degrade into other smaller PFAS. They are used during the manufacturing phase of the different rubber articles to give the finished product special properties, such as avoiding surface corrosion in extreme conditions.
  - The machinery used throughout the entire tyre production, from the rubber compounding phases until the last curing stage, requires strong anti-sticking properties, and for this purpose, fluoropolymer coatings are needed.
- **Fluoropolymers specific properties make them irreplaceable in a series of technological applications, such as in automotive, aerospace, defence, medical devices, semiconductors, industrial machinery and equipment, energy, oil and gas, many of which of great value for European society, being the basis for digital and green transitions, for example, lithium-ion batteries for electric mobility.**

➨ ***Life-cycle assessment:***

- **Fluoropolymers are considered to be polymers of low concern posing negligeable risks to human health and the environment.**
- **The releases to the environment of polymeric PFAS used in rubber goods and the tyre manufacturing process are expected to be low:**
  - during the **manufacturing phase**, **releases appear to be low thanks** to the various risk management measures in place and the professional settings;
  - during the **use phase**, thanks to the stability and non-degradability of fluoropolymers, **no significant amount of non-polymeric PFAS is present in the fluoropolymers** and therefore the release of non-polymeric PFAS could be considered negligeable during the product lifetime;
  - finally, during the **end-of-life phase**, **any potential polymeric PFAS release would mainly be due to the inadequate treatment of end-of-life** general rubber goods articles containing fluoropolymers, as those are treated as industrial waste by professionals.
- **Further measures to address any potential release through the manufacturing of rubber articles and tyres, and through the collection, sorting and process of end-of-life would effectively control the risk for emission of PFAS from rubber articles containing fluoropolymers.**

➨ ***Substitution efforts:***

- **To date, there are no technically suitable and economically viable alternatives. Finding alternatives and substitution (if possible) is highly time-consuming process due to the complexity and to the number of the affected products. This cannot be achieved in the 18-month transition time proposed by the Dossier submitter.**

- In the **GRG sector**, fluoroelastomers, or in general fluoropolymers are used only in applications where operating conditions require their unique properties, and **there are no known alternatives to their current uses where fluoropolymers are crucial to ensuring the safety and durability** of the products.
- In **tyre manufacturing applications**, due to the **unique characteristics of fluoropolymers** (anti-sticking, low coefficient of friction, resistant to wear), **there are no known alternatives** that are currently available for uses of polymeric PFAS, or, more precisely, fluoropolymers, where they are used as lubricants and non-stick coatings, under harsh conditions or for safe functioning and safety of equipment. This use was not identified as such in the restriction proposal.

- **From the general availability of a technically feasible alternative, ETRMA member companies estimated that more than 15 years are necessary to complete transition activities** (i.e., implementing the substitution of PFAS) **from the moment when an alternative is identified, which is not the case.**

➨ ***Socio-Economic impacts:***

- **The total monetized impact of including fluoropolymers in the scope of the proposed restriction on the GRG and tyre industry is estimated at 1.4 billion EUR, including: the total economic impact in the EEA for more than 404 million EUR** and **social costs of unemployment estimated at > 1 billion EUR. The estimates reported in this Impact Assessment report should be considered as a lower bound of the expected impacts of a potential ban. Further analysis is required to provide sector-specific impacts and more precise figures for social and environmental risks.**
- **Therefore, the cost-effectiveness ratio is expected to be considerable and the restriction for the tyre & rubber sector highly disproportionate because only applying to a minor contributor of the total PFAS input in the environment.**
- **Furthermore, the restriction will have wider economic impact such as:**
  - **a major competitiveness loss to many downstream user industries**, such as (non-exhaustive list) automotive, aerospace, defence, medical devices, semiconductors, industrial machinery and equipment, energy, oil and gas.
  - **a loss of competitiveness** as rubber goods made of fluoropolymers for critical strategic applications will not be available for use in the EEA, while still available in the rest of the World.

ETRMA request

Scientific knowledge on polymeric PFAS shows that fluoropolymers are of low concern, being chemically, thermally and biologically stable. Therefore, they should not be included in the scope of the proposed restriction in the same way as non-polymeric PFAS, and major data gaps need to be addressed before any regulatory provision is considered.

If fluoropolymers are not excluded from the scope, considering that the duration of derogations is granted according to the availability of suitable alternatives, a time-unlimited derogation is requested for their placing on the market and uses in the general rubber goods and in tyre manufacturing processes. This request is founded on the absence of any technically and economically viable alternatives to date. It should be noted that a minimum of 15 years would be necessary to transition to any substitute once it becomes accessible, and the socio-economic consequences of such a change would be disproportionate.

Furthermore, such a derogation should be granted to avoid important shortages of tyres and rubber goods which are essential to automotive, health, aerospace and defence, food, energy, oil and gas, marine, nuclear, digital industries. The impacts on society in the EEA could be considered as disproportionate compared to the benefits of this restriction.

All above-mentioned statements are reasonably founded on evidence-based results of a survey, as presented in this report. **It must be noted that the United Kingdom has already excluded fluoropolymers from their PFAS restriction on the basis of the scientific knowledge mentioned above.**
This is a preliminary assessment. **ETRMA is planning a full-fledged SEA** that will be submitted later in the ECHA consultation process.

Purpose and methodology

On 13 January 2023, the Competent Authorities (CAs) of the Netherlands, Germany, Sweden, Denmark, and Norway submitted a joint proposal to ECHA for a restriction under REACH of a broad group of Per- and polyfluoroalkyl substances (PFAS). The proposed restriction aims to limit the risks to the environment and human health from the manufacture, placing on the market and use of a wide range of PFAS through a new entry in Annex XVII of the REACH.[3]

[3]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

The submission proposal has been sent to ECHA, and both RAC and SEAC will provide an opinion. Once this phase is finalised, the proposal and the opinions of RAC and SEAC will be forwarded to the European Commission for decision-making with the Member States in the REACH committee. The entry into force of a potential restriction is currently anticipated to take place at the earliest in 2027 (year of the proposed entry into force of the proposed restriction plus 18 months of transition period).

PFAS are a group of more than 10,000 synthetic (i.e., man-made) chemicals that are ingredients in various consumer and industrial products. The German authorities proposed in May 2017 criteria for identifying such chemicals in the context of EU REACH Regulation (EC) No 1907/2006. Substances meeting these criteria are referred to as either persistent, mobile, and toxic (PMT) or very persistent and very mobile (vPvM), although those properties do not apply to all the chemicals included in the broad OECD definition used as the basis for the current PFAS restriction proposal. Many PFAS are efficient surfactants or surface protectors because of the perfluoroalkyl moiety's high chemical and thermal stability as well as its ability to repel water and oil. As a result, they have been produced in large quantities and used in a variety of industrial, commercial, and consumer applications since the late 1940s.[4, 5, 6]

The main concern of the lead Member State Competent Authorities (MSCAs) regarding PFAS are their high environment persistence, significantly exceeding the very persistent (vP) threshold set out in Annex XIII of the REACH Regulation. Additional concerns emphasised by ECHA are mobility (M) of compounds, as well as long-range transport potential (LRTP), accumulation in plants, and global warming potential.

In line with the **existing official guidance from ECHA on the preparation of the Socio-Economic Analysis,**[7] **this Impact Assessment report aims to gather technical and economic information to describe ex-ante in both qualitative and where feasible, quantitative terms the (orders of magnitude of) socio-economic impacts that the tyre & rubber industry is expected to face from the ban of PFAS.**

It describes the lack of available technologically suitable and economically viable alternatives, the technical difficulties associated with the substitution of fluoropolymers, the social and economic impacts from their restriction, and the broader impacts on society.

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4 Banks, R.E., Smart, B.E., Tatlow, J.C., 1994. Organofluorine chemistry: Principles and commercial applications. New York (NY): Plenum. ISBN 978-1-4899-1202-2.

5 Kissa, E., 2001. Fluorinated Surfactants and Repellents, 2nd Edition, CRC Press. ISBN 9780824704728.

6 Buck, R.C., Franklin, J., Berger, U., Conder, J.M., Cousins, I.T., De Voogt, P., Jensen, A.A., Kannan, K., Mabury, S.A. and van Leeuwen, S.P., 2011. Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. *Integrated environmental assessment and management*, *7*(4), 513-541.

7 The ECHA Guideline for the SEA preparation as a part of Application for Authorization is available at: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e ; The ECHA layout for an SEA to be used in Application for Authorization is available at: https://echa.europa.eu/documents/10162/13637/sea_format_with_instructions_v4_en.docx/0cbc5102-6ba2-2170-480a-0061d2798f55

1. Scientific review of the bases of the restriction proposal

1.1. Analysis of the scope of the restriction

The scope of the restriction proposal applies to the whole class of PFASs, based on the definition proposed by the Organization of Economic Cooperation and Developement (OECD) in 2021[8], according to which a PFAS is any chemical with at least a perfluorinated methyl group *($-CF_3$)* or a perfluorinated methylene group *($-CF_2-$)* (*without any H/Cl/Br/I attached to it*).

The aim of the Authors of the OECD 2021 document was to provide a simple, consistent and coherent definition, which could easily be used also by non-experts, fixing at the same time some issues of the previous definition proposed by Buck et al. in 2011[9].

This resulted in a very broad definition - based solely on some features of the chemical structure - including (thousands of) molecules which show very different chemico-physical and (eco)toxicological properties. As underlined by the Authors:

- there is no correlation between meeting the definition of PFAS and hazardousness: "the term PFAS does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety."
- this definition has to be used with caution: "... PFAS is a broad, general, non-specific term, which should only be used when talking about all the substances included in the PFAS definition described here (or the user should clearly define the scope of which substances are being referred to as PFASs in the documents they prepare)."

A lack of caution would introduce ambiguity and even factual error in the statements. Moreover, the definition was not intended as a base for decisions on how PFASs should be grouped and managed in regulatory or even voluntary actions.

In fact, even structural isomers can show very different properties: this is even more evident for molecules with very different structures. This is acknowledged by the restriction proposal Submitters, who nevertheless justify the grouping approach relying solely on the common property of persistence of the molecules themselves or of their degradation products (so-called arrowheads).

This approach follows the opinion recently expressed by a group of Authors in a critical review[10] and a viewpoint article[11]. However, persistence alone is not necessarily a hazard per se and in fact in REACH

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[8] Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. Series on Risk Management No.61. Tech. rep. Organisation for Economic Co-operation and Development, 2021. url: https : / / www . oecd . org / officialdocuments /publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=En.

[9] Robert C Buck et al. "Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins". In: Integr. Environ. Assess. Manag. 7.4 (Oct. 2011), pp. 513–541.

[10] Ian T Cousins et al. "Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health". In: Environ. Sci. Process. Impacts 22.7 (July 2020), pp. 1444–1460.

[11] Martin Scheringer et al. "Stories of Global Chemical Pollution: Will We Ever Understand Environmental Persistence?" In: Environmental Science & Technology 56.24 (2022). PMID: 36458501, pp. 17498–17501. doi: 10.1021/ acs.est.2c06611. eprint: https://doi.org/10.1021/acs.est.2c06611. url: https://doi.org/10.1021/acs.est.2c06611

Regulation this feature is always taken into consideration together with other properties (e.g. toxicity and bioaccumulation).

Some PFASs - as defined in the proposal - are indeed hazardous, but not because they are persistent (i.e. very stable), or due to some structural elements (such as a $-CF_3$), but due to some chemical functional properties that allow these molecules to exert adverse effects on biological systems.

In order to select a priori the potentially hazardous molecules in a class, such as PFASs, a detailed assessment should be applied. Such assessment should be based on the evaluation of those functional properties which can potentially exert adverse effects. This approach requires the knowledge of the mechanisms that determine the hazardousness of a known molecule with the aim to identify compounds which are expected to exert similar effects on biological systems. This kind of assessment is of course much more complex than a simple structural criterion and it requires the evaluation of a quite large amount of information.

It has to be underlined as well that this approach cannot draw to certain conclusions, which can only be obtained by specific studies, but it allows to classify substances according to their potential hazardousness and take proportionate decisions based on precautionary principle.

Moreover, in addition to the biological action, the tendency of the substance to distribute in the environment - and therefore to reach the target organisms and eventually bioaccumulate - has to be considered as well. The mechanisms through which a substance distributes and moves in the environment depend on its chemical and physical properties and therefore substances having in common only few molecular features (e.g. $-CF_3$ or $-CF_2-$ groups) can have very different environmental fates. Both the hazardousness and the environmental fate of a substance concur to its overall concern, which themselves depend on the physical and chemical features of the individual molecules.

In conclusion, similarity can be considered a valid approach to classify molecules according to their potential concern, based on a predictive assessment, however this assessment requires the evaluation of several elements and cannot be based on just one single structural element (e.g. the presence in the molecule of $-CF_3$ or $-CF_2-$ groups only).

The predictive assessment of the physicochemical, biological and environmental fate properties of compounds from the knowledge of their chemical structure can be supported by mathematical models, such as QSAR, or techniques such as read-across.

At a general qualitative level, it can be observed that PFAS with recognized ability to interact negatively with biological systems are characterized by limited molecular weights (not comparable to polymers' high molecular weights) and the presence of a polar functional group. These features can, for example, be found in the 20 PFAS compounds analyzed in a very recent paper by Beccacece et al. on molecular responses to PFAS exposure[12].

Considering transport mechanisms and consequent environmental fate, remaining at a qualitative level, it can be observed that PFASs, even non-polymeric ones, show in general low solubility in water, which is nevertheless compensated, in certain conditions, by the ability to organize in supramolecular structures, highly mobile in water[13]. These phenomena require a relatively low molecular weight (in

[12] Beccacece, L.; Costa, F.; Pascali, J.P.; Giorgi, F.M. Cross-Species Transcriptomics Analysis Highlights Conserved Molecular Responses to Per- and Polyfluoroalkyl Substances. Toxics 2023, 11, 567. https://doi.org/10.3390/toxics11070567

[13] Jean-Marie Lehn. "From supramolecular chemistry towards constitutional dynamic chemistry and adaptive chemistry". In: Chem. Soc. Rev. 36 (2 2007), pp. 151–160. doi: 10.1039/B616752G. url: http://dx.doi.org/10.1039/B616752G.

the order of 5-20 carbon atoms) and the presence of at least one hydrophilic group (such as, for example, carboxyl, sulfonic, or hydroxyl groups).

1.2. Fluorinated surfactants

PFOA is well known among PFASs, since its ammonium salt was one of the first process additives used for the production of fluoropolymers, together with ammonium salt of perfluorononanoic acid (PFNA). These substances belong to the class of fluorinated surfactants, which are required by emulsion polymerization technique, which has been used for decades to produce plastic fluoropolymers, such as PTFE, and fluoroelastomers, such as FKM.

Fluorinated surfactants are added in an amount of about 1 − 1.5% respect to the polymer. At the end of the polymerization reaction the fluorinated polymer, which constitutes about 25−30% of the emulsion, is separated by coagulation. The majority of the surfactants remain in the aqueous phase, while a negligible part remains in the polymer. The aqueous phase is treated by using the most updated best available techniques (BAT) before being released in the environment, in order to remove the surfactants. In case of potential contaminated sludge waste, this is treated by incineration before disposal.

Considering the hazardousness of these two substances (PFOA, PFNA), the main fluoropolymers producers, taking part to the PFOA Stewardship Program in 2010–2015, committed to their elimination from production processes, substituting them with other surfactants, such as, for example, ammonium salts of carboxylic acids with a per- or poly-fluoroalkyl ether as hydrophobic chain (PFECAs). Due to their chemico-physical properties, these new substances show the same ability to form emulsions in water and a high stability to chemical or biological degradation.

An example is the ammonium salt of hexafluoropropylene oxide-dimer acid (HFPO-DA) that, although maintains the same persistence as PFOA, it has been strongly improved in terms of bioaccumulation level in humans and toxicity, but still raising some concern because of its mobility in water. Other similar examples are the PFECAs, cC6O4 and ADONA.

We therefore acknowledge that the use of fluorinated surfactants in polymerization processes needs the implementation of a careful risk management. Despite improvements have been made in last years to limit environmental exposure, further actions are needed.

At the same time, we underline that the principle that should guide future actions shall avoid regrettable substitutions also by using grouping approach based on chemical and functional similarity. At the same time the future actions should be proportionate measures and be focused on the real issues, avoiding an indiscriminate approach, which would unjustifiably deprive European society of many critical technologies for the realisation of plans considered strategic like digital and green transitions.

1.3. Focus on fluoropolymers and fluoroelastomers

Considering fluoroelastomers, and fluoropolymers in general, they don’t show any chemical similarity with fluorinated surfactants, since:

- due to their high molecular mass these materials are insoluble in water and not bioavailable;
- the lack or the very small amounts of functional groups (compared to the molecular mass) make these materials unable to interact with biological systems (non-bioavailable, non-bioaccumulative and non-toxic).

There is a strong scientific consensus that fluoropolymers satisfy the widely accepted polymer hazard assessment criteria for polymers of low concern (PLC).[14] The PLC criteria encompass various physicochemical attributes, including factors like molecular weight. These attributes influence the substance's ability to enter biological systems and also serve as indicators of potential risks. Fluoropolymers, due to their substantial molecular weight and insolubility in substances like water and octanol, lack the capacity to permeate cell membranes. This characteristic renders them biologically inaccessible, thereby minimizing worries regarding their impact on human health and the environment.

FPs are niche specialty polymers, bio-inert and safe, stable thermally, chemically and very resistant against UV and aging. They fulfil the PLC criteria,[15] and are not prone to generate risks for human safety and environment.[16]

Fluoropolymers used by the rubber industry, such as FKM or PTFE, are chemically, thermally and biologically stable; they do not present significant toxicological concerns and cannot degrade into other smaller PFAS. PTFE has been extensively tested to comply with US and EU food contact and global medical device regulations (e.g., USFDA, CFDA, Korea MFDS, Japan PMDA), including ISO 10993 biocompatibility testing and preclinical animal testing.[17] Its superior anti-sticking properties have been recently confirmed in a simulation study.[18]

Of course, a complete and sound assessment requires an analysis of the whole life cycle of the fluoropolymer, taking into consideration not only the intrinsic properties of the material, but also:

- the properties of the substances used for its production and related emissions;
- the properties and amount of the substances released during use phase;
- the properties of the substances released at the end-of-life cycle.

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[14] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G. and Musio, S. (2023), A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag, 19: 326-354. https://doi.org/10.1002/ieam.4646

[15] The key PLC criterion is a definite range of molecular weight (1,000 - 10,000 g/mol); besides, a polymer of low concern should have a low cationic density, contain approved elements only and not contain any difluoromethylene or trifluoromethyl groups, be stable under the conditions in which it is used and not have any known hazard classification.

[16] Bruno Ameduri, Fluoropolymers: A special class of per- and polyfluoroalkyl substances (PFASs) essential for our daily life, Journal of Fluorine Chemistry, 10.1016/j.jfluchem.2023.110117, **267**, (110117), (2023).

[17] Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, Buxton LW, Fiedler H, Seed J, Hernandez O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag. 2018 May;14(3):316-334. doi: 10.1002/ieam.4035. Epub 2018 Mar 30. PMID: 29424474.

[18] Pan, Deng, Bingli Fan, Xiaowen Qi, Yulin Yang, and Xiuhong Hao. "Investigation of PTFE tribological properties using molecular dynamics simulation." *Tribology Letters* 67 (2019): 1-10.

2. Use of PFAS in rubber goods and tyre manufacturing process

The PFAS uses could be split in four types:

- fluoroelastomers as major ingredients of rubber compounds / articles (presented in section 2.1.2);
- fluoropolymers coatings of non-PFAS materials, e. g., in pharmaceutical packaging / food-contact materials (presented in section 2.1.3);
- BPAF as crosslinking agent in fluoroelastomer compounds (not further discussed below because it is included into an ongoing REACH regulation on BPA)[19];
- fluoropolymers used in the tyre manufacturing process (presented in section 2.2.1).

In addition to the above uses, some fluoropolymer-based pieces and lubricants are also present in the production machinery of both GRG and tyres, not in contact with rubber, but these uses common to all industries will not be specifically developed in this document as this is a preliminary assessment. As a reminder, ETRMA is planning a full-fledged SEA that will be submitted later in the ECHA consultation process.

2.1. Rubber goods and their value chain

The particularities of rubber, with strength, resistance to temperatures and flexibility have made rubber parts essential in many complex goods. For some applications, rubber goods are requested to perform in extreme and hard environments. In these specific applications, rubber needs to be strengthened with fluoropolymers.

It is estimated that **14-50 kilotons of rubber goods require the use of fluoropolymers, accounting for 0.5 to 2% of the overall production** of rubber goods in Europe. More than 22 major downstream industries with their different applications sectors are relying on these specific rubber products for their own productions lines. The key reason why the share of the FP is so small is that fluorinated rubbers are expensive specialty elastomers which are only used in applications in which other (cheaper) rubbers would fail.

Rubber goods containing fluoropolymers are used in (non-exhaustive list):

- Aerospace;
- Automotive Light Vehicles;

[19] In its 2021 Assessment of Regulatory needs ECHA pointed out that the substitution was unlikely for “the subgroup of BPAF and its salts which have intermediate uses and are used as vulcanising agent in fluoroelastomers (synthetic rubber) in industrial settings with low exposure potential”. H and https://echa.europa.eu/documents/10162/c2a8b29d-0e2d-7df8-dac1-2433e2477b02

- Chemical, Pharma & Food End Use;
- Agriculture Equipment;
- CPI Processing Equipment & Machinery;
- Defence;
- Electro-Technical / Electronic;
- Energy;
- Fluid Power;
- Healthcare & Medical (including medical devices);
- Laminated tanks for storage of chemicals;
- Machine Tools / Presses;
- Marine;
- Military;
- Petroleum activities (apart from firefighting foam);
- Raw Material Processing – Pulp;
- Robotics;
- Sanitary Industry;
- Semiconductors;
- Transportation (including Aerospace, automotive, Trucks, Buses, Rail);
- TULAC (gloves, i.e., personal protection equipment);
- Oil & Gas (including mining).

Rubber goods containing fluoropolymers are used inside other complex objects, such as aviation or automotive, in industrial controlled environments or construction sites. Its use is essential to fulfil a modern society needs and cannot be substituted by other alternatives as it would create a breach in rubber goods performance and ultimately an impact on safety and welfare.

The use of fluoropolymers in rubber goods is essential to meet technical expectations on product performance. To date there are not chemicals, nor technological alternatives that could substitute the use of fluoropolymers in the rubber industry.

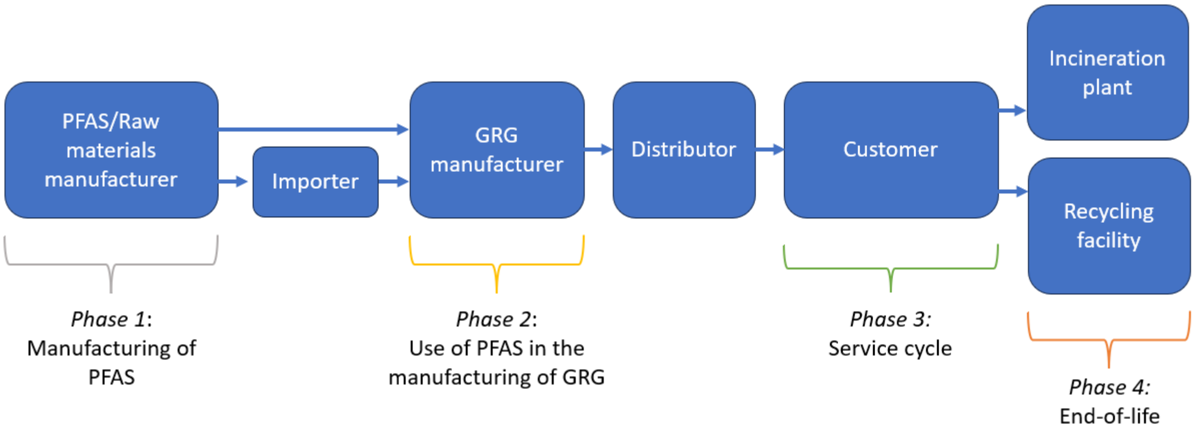


Figure 1: Description of the supply chain for GRG products. Source: ETRMA.

The description of the supply chain provides a general overview of the various players involved in the production of rubber goods containing PFAS. It is also important to note that the GRG manufacturer, although part of the production phase, is not the producer of the PFAS. PFAS are sourced from EEA or non-EEA manufacturers. The customer is mainly a downstream sector company. Finally, at the end of the cycle, end- of- life products are handled by recyclers or incinerators.

2.1.1. Technical functions and performance of PFAS in GRG

Rubber hoses, sealing, gaskets and profiles are used in a large variety of sectors and applications (described in section 2). When those products have to exhibit some specific technical characteristics, the use of fluoropolymers, as FKM or PTFE is required. To date, **there are no substitutes to fluoropolymers that can assure the technical characteristics required to perform in extreme conditions.** Hereunder, there is a list property necessary to provide the technical functionality required.

1. **Low coefficient of friction**

Friction is dependent on pressure, contact surface area, speed and lubrication. Rubber goods containing fluoropolymers do not adhere to surfaces and show only a slight difference between static and dynamic friction, thus eliminating the danger of the stick slip effect in dynamic applications.

2. **Chemical compatibility**

Rubber containing fluoropolymers are stable in all hydraulic fluids including oils.

3. **Temperature range**

Rubber containing fluoropolymers can be used at temperatures between - 253 °C and +300 °C. The materials show no brittleness and have high impact strength, even at low temperatures. Rubber containing fluoropolymers do not change the properties on temperature fluctuations.

4. **High surface speeds**

The good mechanical properties of rubber containing fluoropolymers materials mean they are ideal in dynamic applications, even under extreme loads. Rubber containing fluoropolymers seals offer higher operational reliability than other elastomer seals in dynamic situations, especially in dry starting or operating conditions, as they do not suffer from adhesion or heat generation. When the application is lubricated, seal life will be extended further.

5. Ageing

Rubber containing fluoropolymers materials remain unchanged over extended periods. They are practically non-aging and do not become brittle or degrade, even when subject to severe weathering from heat, light, water or salt spray.

6. Radiation

Rubber containing fluoropolymers, such as RTFP and PCTFE exhibit a good property to electron and gamma radiation and are expected to operate at high radiation doses.

7. Other properties

Rubber containing fluoropolymers have outstanding electrical properties, such as a low dielectric constant or a very high electric strength, even at elevated temperatures. Further, the water absorption of fluoropolymer rubber is < 0.01%.

The use of fluoropolymers in rubber is essential to meet DU's technical requirements. **The key functionalities of fluoropolymers in these specific applications are their chemical and heat resistance as well as inertness (low migration values).**

Rubber goods containing fluoropolymers find application within various complex objects, which are required in controlled industrial environments and in different critical infrastructures (see below section 2.1.2., 2.1.3 and 2.1.4. for the different uses of GRG products). Their use is indispensable to meet the demands of modern society, and they cannot be substituted by other alternatives, as doing so would compromise the performance of the end products and would also lead to serious safety and welfare concerns.

As an example, FP-containing GRG perform well at elevated temperatures where the finished product is expected to have:

Products made with PTFE (Polytetrafluoroethylene)	Products made with FKM (Fluorine Kautschuk Material)	Products made with FVMQ (Fluorosilicone or fluorovinylmethylsiloxane rubber)
Excellent temperature resistance; Excellent oil resistance; Excellent resistance to ozone and external aging; Excellent chemical resistance;	Excellent temperature resistance; Excellent oil resistance; Excellent resistance to ozone and external aging; Excellent DRC (dry rubber content);	Excellent temperature resistance; Excellent tensile strength; Good resistance to ozone and external aging; Good resistance to oils.

Good tensile strength; Good elongation resistance; Excellent friction resistance.	Good chemical resistance; Good tensile strength; Good elongation resistance.	

To summarize, rubber hoses, O-rings, seals, gaskets, bearing pads, expansion joints, profiles and other GRGs are used in a large variety of sectors and applications. When those products have to comply to specific performance and/or safety requirements, the use of fluoropolymers (for example, PTFE, FVMQ, ETFE, FKM, FFKM, and TMF) is necessary because of their unique combination of characteristics.

2.1.2. Main fluoropolymers used in rubber goods

In rubber sector only polymeric PFAS are used intentionally. Fluoroelastomers, such as FKM and FFKM, and fluorosilicones (FVMQ) are used as main constituent (50% - 95%) of certain kinds of rubber articles. A list of fluoroelastomers and other fluoropolymers used in rubber sector is provided in table 1. These specialty polymers are only used when there is no alternative to meet the requirements.

Table 1: Fluoroelastomers and other fluoropolymers used in the rubber sector.

FP	Description
FKM	fluoro rubber having substituent fluoro, perfluoroalkyl, or perfluoroalkoxy groups on the polymer chain
FFKM	perfluoro rubber in which all substituent groups on the polymer chain are fluoro, perfluoroalkyl, or perfluoroalkoxy groups
FVMQ	fluorosilicone rubber
FEPM	copolymer of tetrafluoroethylene and propylene
FEP	copolymer of tetrafluoroethylene and hexafluoropropylene
PTFE	Polytetrafluoroethylene
PCTFE	polymer of chlorotrifluoroethylene
PVDF	polyvinylidene fluoride
PFA	copolymer of TFE fluorocarbon monomers containing perfluoroalkoxy side chains

Fluoropolymers used by ETRMA members for the production of articles, in lower quantities include perfluoroelastomers such as FFKM and PTFE ethylene chlorotrifluoroethylene for manufacturing O-rings for different industrial applications, and other copolymers of the above mentioned such as Polychlorotrifluoroethylene (PCTFE or PTFCE). These specialty polymers are only used when there is no alternative to meet the requirements.

Table 2: Main fluoropolymers used for the production of rubber articles.

Fluoropolymer	Description of the article(s)	Sector(s) of end use
Ethene, 1,1,2,2-tetrafluoro-, homopolymer (PTFE)	Granular PTFE	- Aerospace - Automotive Light Vehicles - Chemical, Pharma & Food End Use - Agriculture Equipment - CPI Processing Equipment & Machinery - Defence - Electro-Technical / Electronic - Energy - Fluid Power - Healthcare & Medical (including medical devices) - Machine Tools / Presses - Marine - Petroleum activities (apart from firefighting foam)/ Oil, gas and mining - Raw Material Processing – Pulp - Robotics - Sanitary Industry - Semiconductors - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Fluoroelastomer (FKM)	Slabs (pre-form)	- Chemical, Pharma & Food End Use - Agriculture Equipment - CPI Processing Equipment & Machinery - Defence - Electro-Technical / Electronic - Energy - Fluid Power - Healthcare & Medical (including medical devices) - Machine Tools / Presses - Marine - Petroleum activities (apart from firefighting foam)/ Oil, gas and mining - Raw Material Processing – Pulp - Robotics - Semiconductors - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Ethylene-tetrafluoroethylene copolymer (ETFE)	Pre-formed	- Agriculture Equipment - Chemical, Pharma & Food End Use - Fluid Power - Petroleum activities (apart from firefighting foam)/ Oil, gas and mining

Fluorosilicone Rubber (FVMQ)	Slabs (pre-form)	- Agriculture Equipment - CPI Processing Equipment & Machinery - Defence - Electro-Technical / Electronic - Energy - Fluid Power - Healthcare & Medical (including medical devices) - Marine - Petroleum activities (apart from firefighting foam)/ Oil, gas and mining - Semiconductors - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Modified Ethene, 1,1,2,2-tetrafluoro-, homopolymer (TFM)	Pre-formed	- Fluid Power - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Perfluoroalkoxy polymer (PFA)	Pre-formed	- CPI Processing Equipment & Machinery - Fluid Power - Raw Material Processing – Pulp - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Perfluoroelastomer (FFKM)	Slabs (pre-form)	- Agriculture Equipment - Chemical, Pharma & Food End Use - CPI Processing Equipment & Machinery - Defence - Electro-Technical / Electronic - Energy - Fluid Power - Healthcare & Medical (including medical devices) - Machine Tools / Presses - Petroleum activities (apart from firefighting foam)/ Oil, gas and mining - Raw Material Processing – Pulp - Semiconductors - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Polychlorotrifluoroethylene (PCTFE)	Pre-formed	- CPI Processing Equipment & Machinery - Energy - Fluid Power - Machine Tools / Presses - Marine - Raw Material Processing – Pulp - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)

Polyvinylidene difluoride (PVDF)	Pre-formed	- CPI Processing Equipment & Machinery
Tetrafluoroethylene-perfluoropropylene copolymer (FEP)	Pre-formed	- Agriculture Equipment - Chemical, Pharma & Food End Use - CPI Processing Equipment & Machinery - Defence - Electro-Technical / Electronic - Energy - Fluid Power - Healthcare & Medical (including medical devices) - Machine Tools / Presses - Petroleum activities (apart from firefighting foam)/ Oil, gas and mining - Raw Material Processing – Pulp - Semiconductors - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Tetrafluoroethylene-propylene copolymer (FEPM)	Pre-formed	- CPI Processing Equipment & Machinery - Fluid Power - Machine Tools / Presses - Raw Material Processing – Pulp - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
Tetrafluoroethylene-propylene copolymer (TFE/P)	Pre-formed	- CPI Processing Equipment & Machinery - Fluid Power - Machine Tools / Presses - Raw Material Processing – Pulp - Transportation (including Aerospace, automotive, Trucks, Buses, Rail)
PVF	Pre-formed	- Laminated tanks for storage of chemicals - Aerospace - Military - Oil & Gas

Besides the use of fluoropolymers in rubber goods, some fluoropolymer-based pieces and lubricants are also present in the production machinery, but they are not in contact with rubber.

The production of General Rubber Goods has been constant over the last years. It is expected that the trend will continue in future, with GRG containing fluoropolymers following a similar trend or even slightly increase possible.

Table 2: Examples of main uses of rubber goods made from or with fluoropolymers.

Product	Field of application	Short description of the product	Industrial, Professional, Consumer use (or a combination thereof)

O-rings, seals	Aerospace	Seals and O-rings in engines and aircraft body	Industrial
Hoses, rubber sheeting	Food Contact	Hoses, seals, rubber sheeting that will be in contact with food products	Industrial
Bearing Pads, expansion joints	Construction Products	Protection of infrastructure due to vibrations, noise, elongation of pipes	Professional
Tubes, seals	Medical Devices, Medical Applications	Tubes and seals in contact with body tissues and fluids	Professional
Seals	Energy Applications	Seals used in windmills, compressors for hydrogen, liquid nitrogen gas, deep sea oil and gas applications	Industrial
O-rings, seals	Transportation	Seals in engines, breaks, safety equipment and suspension.	Industrial, Professional
O-rings, seals, rubber sheeting, hoses	Industrial Applications	Gaskets, process protection, joints, lining of tanks and pipes for corrosion protection	Industrial
Blankets, sheets	TULAC (textiles, upholstery, leather, apparel and carpets)	Dipped textiles to improved water and solvents resistance	Professional
Hoses, Membranes/ tanks	Petroleum (oil & gas)	Storage of petroleum & chemicals	Industrial, Professional
Seals, Hoses	Water and wastewater treatment	Water treatment, wastewater	Industrial, Professional
Adhesive-Mixture	Other (solvents resistant adhesive for metal substrates)	Textile to metal adhesion	Professional

Coated fabrics	Others (chemical resistant clothing)	Protective suits	Industrial, Professional

2.1.3. Fluoropolymers coatings of non-PFAS materials

Other fluoropolymers, such as PTFE or ECTFE can be used as surface coating, in order to reduce friction or to improve surface chemical resistance, or, in powder form, as additive in the rubber compound, mostly for its anti-friction properties.

Table 3: Examples of coating uses of rubber goods made from or with fluoropolymers.

Fluoropolymer	Description of the article(s)	Sector(s) of end use
Ethene, 1,1,2,2-tetrafluoro-, homopolymer (PTFE)	Granular PTFE	- Construction products (e.g., surface treatments (paints, coatings) including lubricants and greases) - Household articles/Consumer mixtures (e.g., non-sticking coating, impregnation agents, polishes etc)
Fluoroelastomer (FKM)	Slabs (pre-form)	- Construction products (e.g., surface treatments (paints, coatings) including lubricants and greases) - Household articles/Consumer mixtures (e.g., non-sticking coating, impregnation agents, polishes etc)
Ethylene-tetrafluoroethylene copolymer (ETFE)	Pre-formed	- Construction products (e.g., surface treatments (paints, coatings) including lubricants and greases)
Fluorosilicone Rubber (FVMQ)	Slabs (pre-form)	- Construction products (e.g., surface treatments (paints, coatings) including lubricants and greases) - Household articles/Consumer mixtures (e.g., non-sticking coating, impregnation agents, polishes etc)
Perfluoroelastomer (FFKM)	Slabs (pre-form)	- Household articles/Consumer mixtures (e.g., non-sticking coating, impregnation agents, polishes etc)
Tetrafluoroethylene-perfluoropropylene copolymer (FEP)	Pre-formed	- Construction products (e.g., surface treatments (paints, coatings) including lubricants and greases) - Household articles/Consumer mixtures (e.g., non-sticking coating, impregnation agents, polishes etc)
Tetrafluoroethylene-propylene copolymer (FEPM)	Pre-formed	- Household articles/Consumer mixtures (e.g., non-sticking coating, impregnation agents, polishes etc)

Fluoroelastomer(FKM)	Slabs, pre-formed	- Rubber coated fabrics used for protection and safety

2.1.4. Examples of downstream uses of rubber goods

To analyse the GRG value chain, it is essential to understand the uses made of GRG products by downstream users. Whether in the automotive, aerospace, medical, energy, electronics or construction sectors, rubber products containing PFAS are required at many stages, in many industries. Therefore, here is a non-exhaustive list of the different uses made by downstream users of GRG, as well as an explanation of the technical specifications that require these PFAS-containing products.

2.1.4.1. Automotive

The automotive industry is a major downstream user of FP-containing rubber goods. In particular, fluoropolymers are used for several key components, such as gaskets, hoses, joints, O-rings and seals. These rubber goods should meet the technical requirements for aggressive media and high temperatures, up to 275 °C.

Fluoropolymer-based rubber components are used in many automotive applications, the main ones being turbochargers, sealing elements for electrical motors, intake manifold seals, fuel pump seals, fuel injector seals, fuel filter seals, quick connectors seals, turbocharger seals, EGR seals, fuel tank seals, engine cooling system and thermal management seals, power steering, powertrain (transmission and clutch), rotary shaft seals, components for transmissions, components for power transfer units (PTU), EGR's or Secondary air valves used in car/truck, shock absorbers for high temperatures and in contact with oils, other components for automotive / agricultural vehicles / marine diesel engines, sealings for gas injectors, membranes for gas regulators, sealings for oil filters, sealings for cooling systems, etc.

For instance, the use of different types of FKM for specific car components is required by many specifications of car manufacturers (VW, BMW, Mercedes, Stellantis, etc.) or by subcomponents manufacturers (Bosch, Mann& Hummel, Siemens, etc.).

FKM and FFKM have the broadest resistance ranges according to ASTM D 2000 "Standard Classification System for Rubber Products in Automotive Applications" HK class material. Their use was key for a series of technological achievements which allowed to meet the more and more stringent EU environmental standards. FKM are also necessary in applications such as sealings for rotary shafts: in a wet / dirty environment rotary shaft seals keep lubricant (oil, grease or water) inside the application and prevents ingress of water and dirt.

Modern combustion engines, designed to maximise efficiency and cut emissions, are characterized by operating conditions in which only fluoroelastomer components can resist. In other words, FKM are key for the reduction of fuel consumption, CO2 emissions, VOC emissions (from fuel tanks and lines), particulates and NOx emissions.

Fluoropolymers/fluoroelastomers are also used in batteries and fuel cells, key components of the EU zero-emission policy.

A non-exhaustive inventory of the fluoropolymers used in the automotive industry conducted recently by ACEA identified more than 250 parts composed entirely of fluoropolymers/fluoroelastomers, half of them located in the engine. Many critical components of any car, for instance, joints, seals, tubes, O-rings, and gaskets, are FR-containing or FT-made rubber goods.

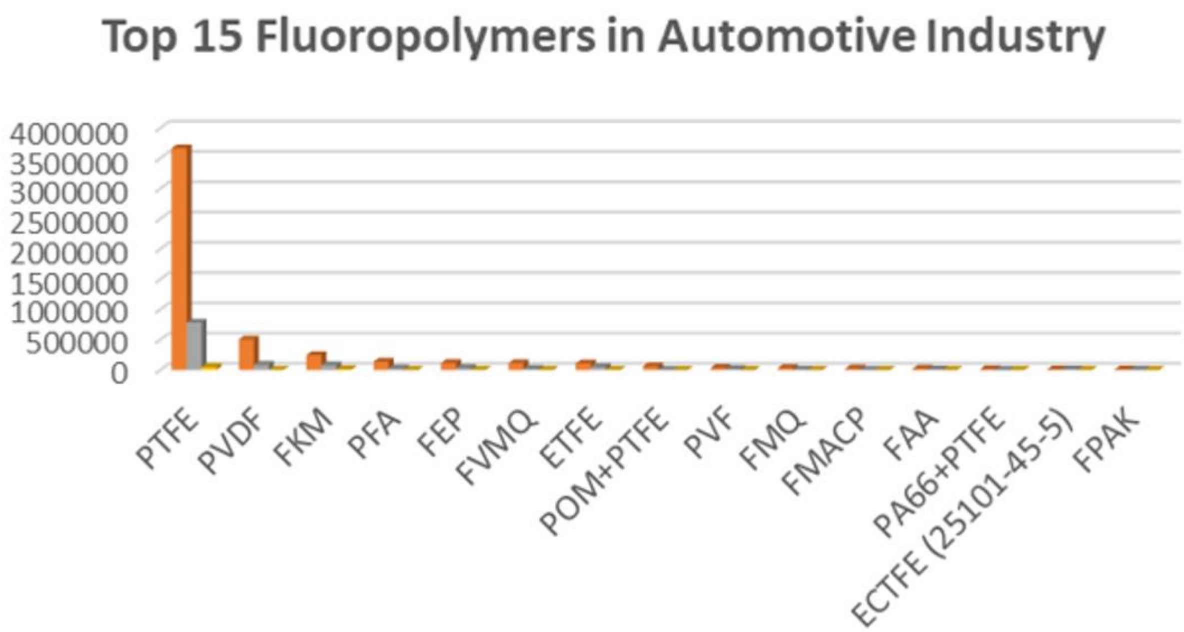
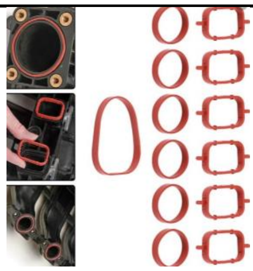
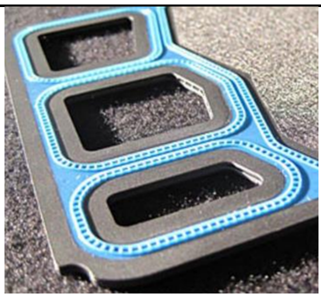
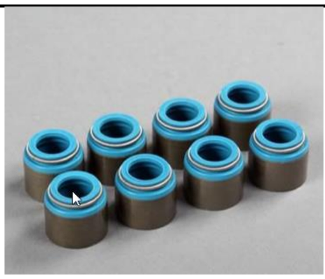


Figure 2: Top 15 fluoropolymers in automotive industry. Source: ACEA.

Here are some examples of rubber articles that contain fluoropolymers and are critical for ensuring safety of cars.

	**Gaskets**
	**Hydraulic hoses**

	**O-rings used as seals in fuel containment systems and fuel injectors**
	**Shaft seals and valve stem seals**
	**Air intake manifold gaskets**
	**Sealing plates**
	**Cylinder head gaskets**

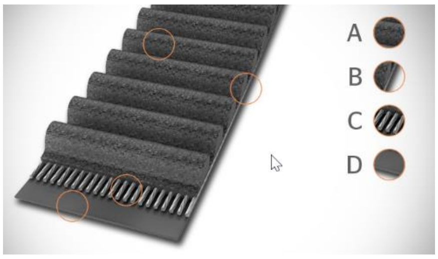
	**Automotive venting products**
	**Hoses lines for Diesel and gasoline particular filter** – to reduce particulate emissions from diesel engines. Hose lines featuring sensor technology for the exhaust filter cleaning of diesel and gasoline engines form the interface between the particulate filter and the control unit.
	**Toothed V-ribbed belt** where: A) Polyamide fabric, sometimes also on the belt backing; B + D) Synthetic rubber, sometimes fiber-reinforced with fluoropolymers; C) Tension member made of glass-fiber.

Figure 3: Examples of fluoro rubber articles used by automotive industry. Source: ETRMA.

2.1.4.2. Aerospace

For aerospace industry the key products are rubber seals and O-rings inside engines, landing gear and window frames, where fluoropolymer-based components are in contact with either oils at high temperature and extreme pressures, or extremely low ambient temperatures in the case of window frames and landing gears in airplanes. There are no alternative materials to these applications today, so using fluoropolymers is the only way to keep airplanes flying.

Rubber containing fluoropolymers are required for sealing and O-rings inside aircraft that must resist extreme conditions. Whether this is to maintain pressure, prevent leakage or keep temperature constant, many aspects of a modern plane rely on the presence of rubber gaskets and seals. The use of fluoropolymers is essential to do not compromise safety, as they offer to rubber the required durability and strength.

Mandatory standards, which are binding for the aviation industry, require the use of fluoropolymers in rubber to meet the technical characteristics, for instance:

- Aerospace standard, gland design, O-ring, and other elastomeric seals AS4716: This SAE Aerospace Standard provides standardized gland (groove) design criteria and dimensions for elastomeric seal glands for static and dynamic applications. The glands have been specifically designed for applications using SAE AS568 size O-rings at pressures exceeding 1500 psi utilizing one or two anti-extrusion (backup) rings and applications at pressures under 1500 psi without backup rings. The glands have been sized to provide sufficient squeeze for effective sealing while at the same time limiting squeeze to allow satisfactory operation in dynamic applications. While specifically designed for standard size O-rings, these glands are also to be used with other elastomeric seals.

- Gland Design, O-ring and Other Elastomeric Seals, Static Applications AS5857: This SAE Aerospace Standard (AS) provides standardized gland (groove) design criteria and dimensions for elastomeric seal glands for static applications. The glands have been specifically designed for applications using SAE AS568 size O-rings at pressures exceeding 1500 psi (10.3 MPa) utilizing one or two anti-extrusion (backup) rings and applications at pressures under 1500 psi (10.3 MPa) without backup rings. The glands have been sized to provide increased squeeze as compared to AS4716 for more effective sealing at low temperatures and low seal swell conditions. These glands are not recommended for dynamic use. Primary usage is for static external sealing.
- Face Seal Gland Design, Static, O-ring and Other Seals for Aerospace Hydraulic and Pneumatic Applications AS6235: This SAE Aerospace Standard (AS) specifies standardized gland design criteria and dimensions for static face seals for internal pressure and external pressure applications for aerospace hydraulic and pneumatic applications using the same size range as AS4716 and AS5857 where applicable. Some small diameter sizes are excluded because they are not practical.

  The glands have been specifically designed for applications using AS568 size elastomeric O-rings with related Class 2 tolerances at nominal system operating pressures up to 3000 psi (20 680 kPa) utilizing no anti-extrusion (backup) rings.

  While the gland dimensions herein have been designed for pressures up to 3000 psi (20 680 kPa) these glands may be used for higher pressures, but extra precautions need to be taken and testing should be performed to ensure to ensure integrity of performance.

  This specification covers the basic design criteria and recommendations for use with standard size elastomeric O-rings, however, these glands are also suitable for use with other elastomeric and polytetrafluoroethylene (PTFE) based seal geometries.

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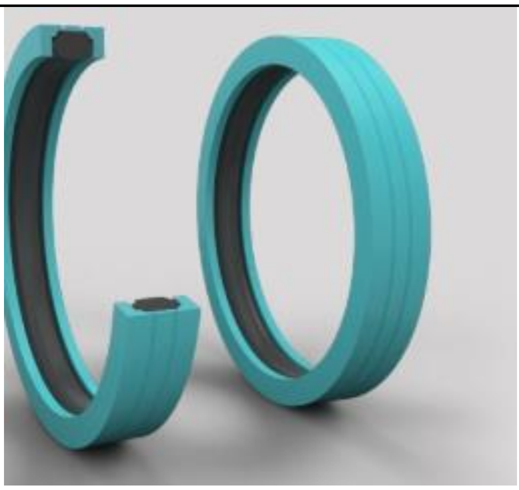
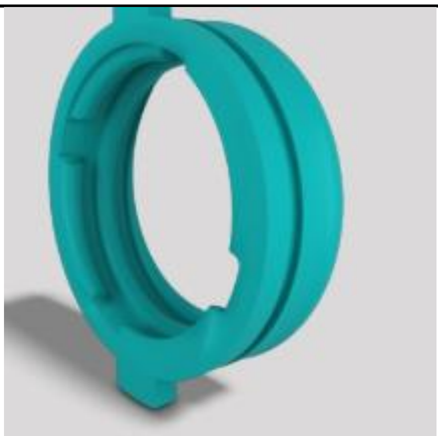
	**Sealing**
	**O-rings**
	**Flight safety solutions**

Figure 4: Examples of fluoro rubber articles used by aerospace industry. Source: ETRMA.

2.1.4.3. Medical devices and medical applications

Due to the aggressive chemical substances and radiation treatment used for cleaning and disinfection of the medical equipment, fluoropolymers, with their chemical resistance, are crucial for these applications. Phasing-out fluoropolymers would compromise the reliability of the manufacturing processes in the pharmaceutical industry and would have far reaching implications for healthcare sector, and ultimately for the health and safety of patients.

Figure 5: Implantable medical devices. Source: ETRMA.

The main fluoropolymers used in medical devices and medical applications are PTFE, FKM, Fluorosilicone Rubber (FVMQ), Perfluoroelastomer (FFKM) and FEP. Bisphenol AF is also another important PFAS (non-FP) for medical devices and medical applications.

FFKM in particular is a universal material used in a wide variety of applications that require outstanding performance. Ideal for process systems requiring intensive CIP (Cleaning In Place) and SIP (Sterilization In Place) regimes or aggressive process media. It is especially suitable for O-rings and custom designs.

FFKM has unrivalled chemical and thermal resistance as well as other properties critical for medical applications:

- Temperature resistance from -25 °C to +325 °C;
- Combines the advantages of an elastomer with the chemical resistance of a PTFE;
- Almost universal chemical compatibility;
- Materials perform well in a broad range of chemical media including ethylene oxides, acids, alkalis, amines, esters and steam;
- Exceptional hysteresis properties;
- Outstanding low long-term compression set characteristics;
- High purity, low contamination from extractables;
- Complete traceability;
- Reduce downtime and improve production efficiency;
- Sealing effectively under pressure or in a vacuum;
- Materials compliant to FDA 21 CFR.2400 (d), 3-A, USP Class VI, Cytotoxicity (USP 87).

FKM is typically used for healthcare and medical applications when manufacturing mechanical seals, decanters, separators, pumps, tanks, valves, heat exchangers and equipment cleaned using clean-in-place and sterilize-in-place regimes. FKM can be bonded to other materials and delivered as engineered parts in almost any design.

Its key properties are as follows:

- Temperature resistance from -20 °C to +220 °C;

- Steamable FKM up to +170 °C;
- Very good chemical compatibility and resistance;
- Good compatibility with acidic fluids, fatty food products, food grade lubricants and oils;
- Low total organic carbon and metal extractables;
- Low long-term compression set characteristics;
- Material compliant to FDA 21 CFR177.2600, 3-A, USP Class VI, Cytotoxicity (USP 87).

Products designed for medical purposes must be safe for patients, especially when these products come into contact with a patient’s body, and even more so when products are implanted for long-term use. Unique properties of fluoropolymers are necessary to ensure safety of tubes, hose fittings and seals in contact with body tissues and fluids. In particular, this is crucial for anti-microbial tubing, which is of an utmost importance to reduce hospital acquired infections and transmission of germs.

PTFE sheeting and film serve a variety of medical uses, including reinforced sheeting for artificial heart valves. This sheeting can be used as a flat sealing element in medical applications by punching or cutting it into particular shapes, Sheeting can be reinforced with various materials and can be punched or cut into any desired geometry.

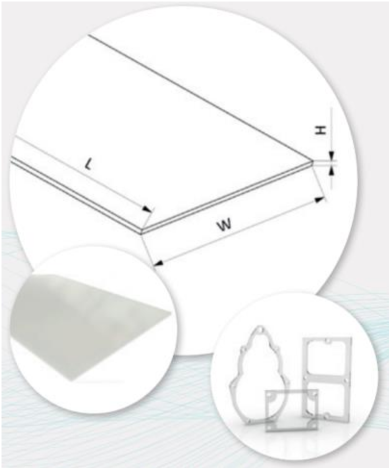


Figure 6: Custom-made PTFE sheets. Source: ETRMA.

Fluoropolymer barrier coatings are irreplaceable for primary packaging of many medicinal products. FP-coated stoppers can provide a good example. FP coated halobutyl rubber closures are used as vial stoppers or syringe pistons for highly sensitive injectable drugs. It is estimated that 20% of all injectables drugs are manufactured with FP barrier coated rubber. A further increase of FP coated rubber closures is expected in the future because innovative drugs are more and more difficult to stabilize.

FP-coated stoppers are referenced in the relevant pharmacopeial sessions like e.g., US Pharmacopoeia <381> “Elastomeric Closures for Injections” (in short USP <381>) and the European Pharmacopoeia 3.2.9 “Rubber Closures for Aqueous Parenteral Preparations, for Powders and for Freeze-Dried Powders” (in short EP 3.2.9.).

FP coated stoppers are part of the primary packaging of a medicinal product. That means they are part of the stability program at the pharmaceutical company and hence part of the certification procedure by the health authorities. Approval times may vary between 2 up to 7 years.

Table 3: Uses of fluoropolymers in stoppers.

Fluoropolymer	Description of the article(s)	Sector(s) of end use
ETFE film	Halobutyl stopper is covered with a ETFE film to create an inert barrier coating between rubber and drug medicine.	Parenteral/Injectables primary packaging components for containment of sensitive drug medicine intended to be injected, e.g., oncology, cell-and-gene, biological based drugs, and other medicines sensitive to migrating substances from the rubber.
PVDF	Halobutyl stopper spray coated with FP solution to create an inert barrier coating between rubber and drug medicine.	Parenteral/Injectables primary packaging components for containment of sensitive drug medicine intended to be injected, e.g., oncology, cell-and-gene, biological based drugs, and other medicines sensitive to migrating substances from the rubber.

FP coating on closures (grey) serves as inert barrier coating for extractables and prevents leaching from the rubber into the medicine.

Vial

Prefilled Syringe

Figure 7: Example of a FP barrier coating. Source: ETRMA.

The FP used has a high inertness towards drug medicines and acts as a barrier material for the Rubber stopper substrate. The figure below shows the barrier effect of a FP coating on the extractable/migrating chemicals from a rubber.

The graph represents 2 spectra in mirror effect: above the 0-line the coated rubber, below the 0-line the same but uncoated rubber. Each peak represents an impurity or raw materials migrating out of the rubber. The height of the peak represents the amount migrating out of the rubber.

It is clearly visible that the coating not only reduces the amount coming out of the rubber, but in many cases even completely eliminates the impurities coming out.

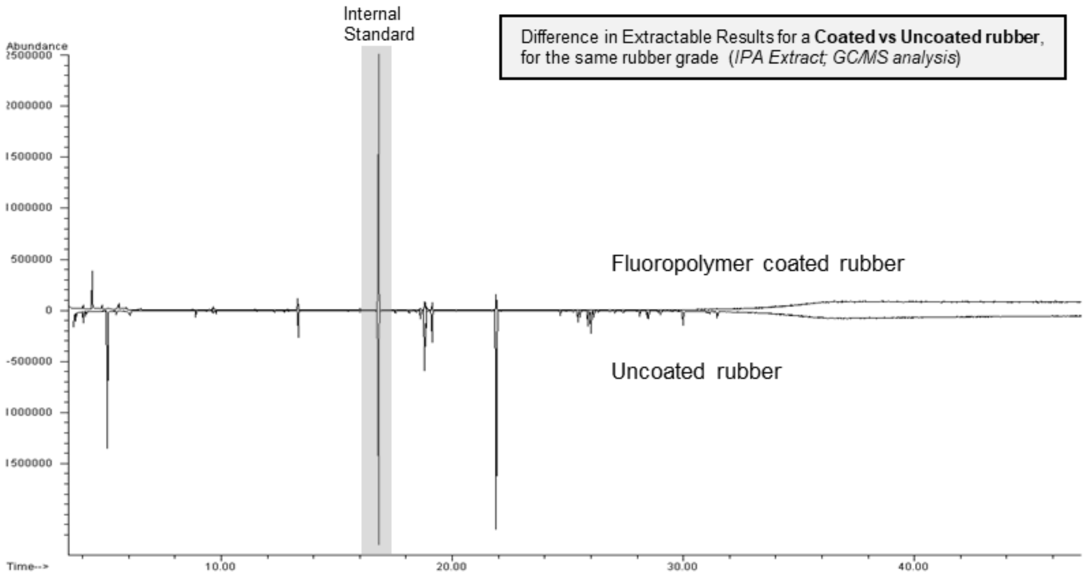


Figure 8: Difference in Extractable Results for a Coated vs Uncoated rubber. Source: ETRMA.

For many drug formulations, in particular the more recently developed (e.g., mRNA vaccines like against COVID, oncology, biological based drugs and cell-and-gene therapies), impurities coming from rubber may jeopardize the stability and effectivity of the drug itself and need to be studied and controlled in ageing stability studies. In many cases, the uncoated version fails such stability study, and the coated rubber is the only option left. Besides, each impurity needs to pass a safety and toxicological assessment. That's why pharma companies need a rubber closure with the cleanest extractables profile, i.e., the FP-coated version.

The halobutyl substrate is a first prerequisite for medicinal rubber closures as they have the lowest permeability for air and moisture and can be chemically seen be crosslinked in a clean way. The additional FP coating (via film deep drawing or via tumble spray coating) applied on top of the halobutyl functions as a barrier for the remaining chemical substances that can migrate from the rubber stopper (e.g., oligomers, antioxidants, plasticizers, cross linking residues). Also, the FP coating is inert on itself, to avoid additional adverse reactions with the drug medicine.

The FP coated stoppers have proven their performance throughout the years: where expensive stability studies of new drugs by the big Pharma failed in combination with a standard halobutyl stopper, the FP-coated version was successful.

2.1.4.4. Other sectoral uses

Chemical industry: e.g., O-rings, sealing elements, hoses and other components installed in machinery for the production of chemical products (in contact with aggressive fluids at high temperatures), hermetic sealings for containers of hydrocarbon derivatives, sealing applications in valves for gases (such as methane or hydrogen), sealings used in devices for transportation of chemicals (e.g., used to treat metals), sealing for galvanization process devices, perimetral gaskets for chemical plants, expansion joints, etc.

As an example, FKM, FEPM and FFKM seals are widely used in chemical industry as critical safety components in pumps, compressors, mechanical seals, flanges, etc. for their unmatched combination of thermal stability and chemical inertness in complex chemical mixtures. They enable the global chemical industry to operate in safe conditions, reducing fugitive emission to ground, air, and water as well as minimizing exposure of emissions to facility staff. Their long-term reliability allows to increase both mean time between failures (MTBF) and mean time between repairs (MTBR), making the process industry safer and reducing its operating costs at the same time.

Oil & gas: e.g., explosive decompression resistant seals for mining and drilling applications, gaskets, hoses, profiles, sealings for pipes, valves, and joints, etc.

For natural gas applications, European standard EN549 defines the requirements for different types of rubber materials for seals and diaphragms for gas appliances and gas equipment. In particular, the requirements for Classes E1, E2, E3 and E4 (up to 150 °C operating temperature) can only be met when using FKM materials. Standard EN549 is currently under revision to prepare rubber parts for the progressive feeding of gas supplies with green hydrogen (The European Clean Hydrogen Alliance, ECH2A). FKM is part of this transition because it is ideal for the very low permeability to gases.

FKM, FEPM and FFKM are widely used in gaskets and hoses for oil & gas applications (drilling, completion, and production), mainly due to their resistance to most hydrocarbon-based substances. They are expressly requested by the specifications of a number of service companies (BH, Schlumberger, Weatherford, Halliburton, etc.) as well as by the oil majors (Shell, Total, Saudi Aramco, Exxon, BP, etc.).

Food contact: e.g., O-rings, gaskets, sealings for static and dynamic applications, hoses, profiles, etc. These components can be used to manufacture consumer articles (for example household appliances, such as immersion mixers), or, more frequently, industrial plants for foodstuff processing (for example stators for progressive cavity pumps used in food industry).

FKM and FFKM are much used in food contact applications. They are used to manufacture components, such as sealings or hoses (inner tubes), which are widely used in food and beverage processing equipment, such as pumps, mechanical seals and flanges connecting metal pipes. Their inherent thermal and chemical stability make them the only technical solution for high demanding applications like SIP (steam-in-place) and CIP (clean-in-place) processes for cleaning and sterilization of equipment.

Moreover, FKM and FFKM are well known for their intrinsic higher level of purity, or more precisely, for a very low overall migration level, thus minimizing the risk of contaminating the processed food.

The use of fluoroelastomers for food contact applications is foreseen by the main regulations for food contact materials, such as US FDA (21CFR 177.2600 and 21CFR 177.2400) and German BfR Recommendation XXI/1, which impose acceptance limits.

Their usage has been constantly growing over the last few years because of the implementation of stricter regulations to defend consumer's health (lower migration into the food streams) and of the use of more severe conditions for cleaning and sterilization of food processing equipment and plants.

Semiconductors / electronics: gaskets, profiles, hoses, sealings (for example used in devices for transportation of ultra-pure water), O-rings, etc. used in buffer, semiconductor and chipset production plants and machineries (i.e., photolithography, etching, etc.

Fluoropolymers are extensively used in semiconductor manufacturing process chambers, mainly due to:

- resistance to plasma (in the etch and deposition processes as well as in plasma chamber cleaning processes),
- high purity (low release of organic and metallic contaminants along with low particle shedding),
- high temperature resistance (some deposition processes, such as PECVD, operate at temperatures above 250◦C).
- very low permeability.

FKM and FFKM seals are also critical safety components of ancillary equipment (such as vacuum pumps) and in the subfab effluent treatment systems that are designed to abate highly toxic gases and that usually operate at high temperatures (above 250◦C) to avoid condensation and the formation of potentially dangerous deposits in the ductwork.

Fluoropolymer based elastomeric seals are therefore critical elements in wafer processing equipment, enabling continuous improvements the electronics technology and therefore increasing digitalization. At the same time, they allow safe and effective operation of the semiconductor fabs, thus contributing to minimize emissions and ultimately the environmental impact.

They are also used in tools for the transportation of ultra-pure water for the production of semiconductor waivers.

Energy applications, including batteries and hydrogen: e.g., hoses, gaskets used in electrical devices, switches, batteries, electric motors, connectors, components of marine diesel engines (for power generation), boilers (in contact with condensates and flames), components used in the transmission of wind turbines (in contact with greases at high temperatures), sealing solutions for gas, valves, etc.

Lately, fluoroelastomer seals are getting more and more used by the alternative energy sector, such as hydrogen storage and transportation due to their low hydrogen permeation rate. In tests conducted in high pressure hydrogen at an independent lab FKM showed the lowest hydrogen permeation rate among other types of elastomers (EPDM, HNBR, NBR, silicones). Fluoroelastomer seals are also present in hydrogen manufacturing in electrolysers, due to their combined temperature and chemical resistance.

In the short to medium term most of the global hydrogen production will still rely on steam reforming of natural gas followed by carbon capture, utilisation and storage (CCUS), the so-called blue hydrogen process. That's why the role of FP is even more important, since exploration and exploitation of gas deposits with high concentrations (up to 40%) of H2S can only be safely conducted when using special types of fluoroelastomer seals.

Besides, FKM, FEPM and FFKM-based seals are also being developed for future applications in deep geothermal wells where high temperature water and steam (typically more than 220◦C, in some cases between 250 and 300◦C) are extracted from stimulated fractured rocks. There is no other sealing material able to withstand water exposure at such operating temperatures.

Cosmetics & personal care: e.g., O-rings for spray cans or other sealing elements, hoses used in manufacturing phase.

Construction: e.g., components for tanks, drills, filters, press fittings, O-rings, gaskets, sliding elements, bearings, thermal expansion joints (e.g., for railway bridges).

Metal plating and manufacturing of metal products: e.g., rubber coating for metal rolls to be used in metal lamination process.

Earth moving and agricultural machinery / marine transmission: e.g., rotary shaft seals, household appliances: e.g., gaskets, membranes and other technical articles (ex. washer sleeve) used in domestic appliances (for example, washing machines).

Hydraulic and pneumatic: e.g., gaskets, check valves, membranes. Water and wastewater treatment: hoses, gaskets, sealing components for drinking water plants / water conveying systems.

Fashion sector: e.g., watch stripes, crown, pusher, case made with FKM or covered with FKM.

However, this list and section is only an overview, as the downstream uses of rubber containing PFAS are innumerable and it seems almost impossible to identify them all. ETRMA therefore stresses the preliminary nature of this list and the importance of a better understanding of value chains and the use of PFAS in GRGs.

2.1.5. Tentative life-cycle analysis for GRG sector

As outlined in section 2.1. (see figure 1), the primary issue is associated with the utilization of fluoropolymers in the GRG production process. Fluoropolymers contain minimal non-polymeric PFAS content, which means that non-polymeric PFAS compounds are not discharged during subsequent processing stages or throughout the product's lifespan. Similarly, when it comes to the end-of-life phase of these products, the emissions of PFAS can be regarded as negligible since they are either incinerated or recycled.

Many efforts have been made in last years by fluoropolymers producers in order to improve and develop the best available techniques in the manufacturing process, with the aim to manage the environmental emissions.

Moreover R&D projects are being carried out by some major manufacturers with the aim of replacing fluorinated PAs with non-fluorinated PAs; another possibility is to find a way for producing fluoropolymers without the use of any processing aid.

- **Phase 1: Manufacturing of PFAS**

The main concern is linked to the manufacturing phase and is not related to the fluoropolymer itself, but to the use (and related emissions) of processing aids: mainly non-polymeric PFAS substances, which can be transported in water bodies.

Many efforts have been made in last years by fluoropolymers producers in order to improve and develop the best available techniques in the manufacturing process, with the aim to manage the environmental emissions. Important results have been reported by major manufacturers, such as fluorinated processing aids (PA) recovery for reuse, 99% removal of fluorinated PA in wastewater treatment, 99.99% capture and destruction efficiency of gaseous emissions through a thermal oxidizer[20]. Thanks to these new risk control techniques, it can be estimated that PFAS emissions during the production phase are minimal.

Some preliminary results show that fluoropolymers obtained making use of non-fluorosurfactant technologies, without the use of any surfactant, shows un-detectable (LOQ = 1.0 ng/g) content of perfluoroalkylcarboxylic acids and per-fluoroalkanesulfonates. These results demonstrate that it is possible to exclude the risk of formation of fluorinated short-chain PFAS of concern during polymerization.

Other ongoing R&D projects are aimed at the substitution of emulsion polymerization with other technologies, for example the polymerization in suspension already experimented by Asahi (US 4985520). This technology was later updated in order to increase reaction rates and improve distributions of molecular weights, which has important effects on the subsequent processability of the polymer. On the other hand, also the use of non-fluorinated surfactants is known to decrease reaction rates, but even in this case, further research could lead to interesting results.

In any case, GRG industry, committed to a continuous increase of safety and reduction of environmental impact, is ready to face the investments required by the adoption of these cleaner technologies.

- **Phase 2: Service life of the GRG**

The assessment drawing to the conclusion that fluoropolymers are Polymers of Low Concern[21] allows to assume that no significant amount of non-polymeric PFAS is present in the fluoropolymers and therefore non-polymeric PFAS are not released during subsequent transformation stages and during product lifetime.

Moreover, in fluoroelastomers crosslinking among polymeric chains - and consequent formation of a continuous elastomeric network - suppresses the general mobility of medium-low molecular weight substances present in the material (Stephen H. Korzeniowski et al.).

Fluoropolymers are distinctly different from other polymeric and non-polymeric PFAS due to their thermal, chemical, photochemical, hydrolytic, oxidative and biological stability. They have negligible

[20] Stephen H. Korzeniowski et al. "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers". In: Integrated Environmental Assessment and Management 19.2 (2022), pp. 326–354. doi: https://doi.org/10.1002/ieam.

[21] Stephen H. Korzeniowski et al. "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers". In: Integrated Environmental Assessment and Management 19.2 (2022), pp. 326–354. doi: https://doi.org/10.1002/ieam. 4646.

residual monomer and oligomer content and low to negligible leachability; they are extremely pertinent, have different safety and environmental considerations, unique and intrinsic properties and are largely deployed as raw material in various industries. Contrary to other PFAS, fluoropolymers are considered to be non-mobile in the environment, not bio-accumulative and unable to bioconcentrate. Stability studies reported reveal fluoropolymer stability in terms of light, hydrolysis, heat, oxidation, and biodegradation (Stephen H. Korzeniowski et al.). Little or no data has been found as regards adsorption/desorption of fluoropolymers, their presence in sewage and soil and volatilization.

Thus, the primary focus remains non-polymeric PFASs from the manufacturing process or fluoropolymer degradation during end-of-life disposal.

- **Phase 3: End-of-life**

According to a recent End-of-life (EOL) analysis performed by Conversio[22], almost 84% of all fluoropolymer applications are incinerated at the end of their life in energy recovery or thermal destruction processes. The remaining of the collected fluoropolymer waste is landfilled ($\simeq$ 13%) or recycled ($\simeq$ 3%).

As regards landfilling, it should be noted that since fluoropolymers are chemically, thermally, and biologically stable (Henry et al., 2018; Korzeniowski, et al. 2022), they are not expected to transform to dispersive nonpolymeric PFAS when disposed of in a landfill. A recent study presented results from OECD guideline biodegradation studies demonstrating that PTFE is stable and does not degrade under environmentally relevant conditions (and is not expected to significantly contribute to landfill leachate[23]).

The possible formation of PFAS (short chain or long chain) during incineration of fluoropolymers was investigated in a peer-reviewed study published in Chemosphere[24]. The study concluded that at the typical conditions foreseen by best available technologies, municipal incineration of PTFE is not a significant source of PFAS.

Further investigation was recently performed by Karlsruhe Institute of Technology (KIT)[25], that analysed incineration of post-use samples containing four different fluoropolymers, including fluoroelastomers (PTFE, PVDF, PFA, FKM). This study provides strong evidence that incinerating a mixture of fluoropolymers under representative municipal waste combustion conditions leads to complete mineralization of the C-F bonds, no significant emissions of long-chain PFAS, and no significant emissions of TFA or light fluorocarbons such as CF4 or C2F6.

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[22] Fluoropolymer waste in Europe 2020 - End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams. Tech. rep. Conversio, June 2022.

[23] Ruwona and Henry. (2021). PTFE: Persistence without hazard at environmentally relevant temperatures and durable by design. Fluoros 2021, Providence, RI.

[24] Krasimir Aleksandrov et al. "Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas". In: Chemosphere 226 (2019), pp. 898–906. issn: 0045-6535. doi: https://doi.org/10.1016/j.chemosphere.2019. 03.191. url: https://www.sciencedirect.com/science/article/pii/ S0045653519306435.

[25] Hans-Joachim Gehrmann et al. Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions. Tech. rep. Karlsruhe Institute of Technology, 2023.

2.2. Tyre products and their value chain

ETRMA tyre company members represent 70% of the global tyre sales. The industry has a strong presence in the EEA with 86 tyre-producing plants and 16 R&D centres. It is estimated in close 5.1 billion tons of the production of Tyres in Europe.[26]

Over 200 raw materials go into tyre's composition, and none of them are PFAS. The first stage in the tyre manufacturing process is mixing raw materials to form the rubber compound. The uncured rubber compounds are then extruded, calendared and finally cured in order to produce the tyre. Due to the unique manufacturing process, the uncured parts need to show proper tackiness in order to be able to adhere to each other during the assembly process. For this reason, the machinery used along the entire tyre production, from the rubber compounding phases until the last curing stage, requires strong anti-sticking properties, and for this purpose, fluoropolymers are irreplaceable.

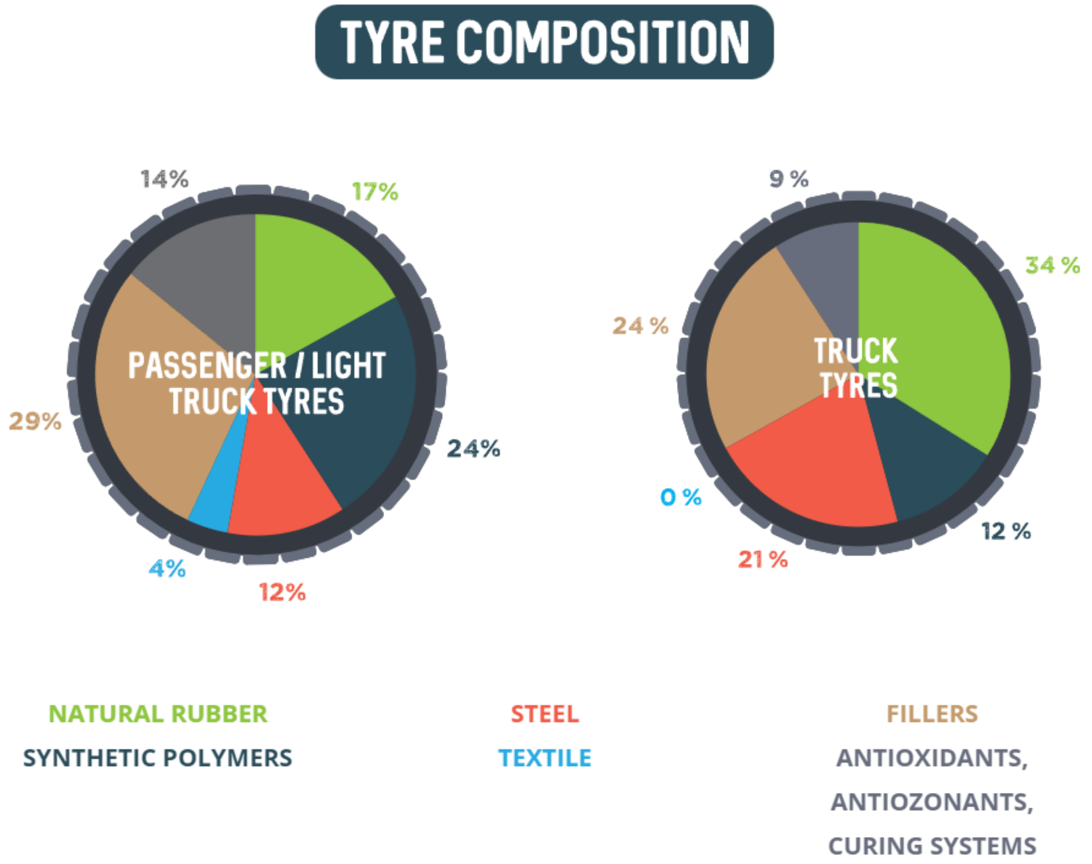

Figure 9: Tyre composition. Source: ETRMA.

High-specialised machineries are essential to manufacture tyres to prepare the different kinds of semi-finished materials required in tyres production: inner liners, textile plies for casing plies and textile belt plies, metallic plies for belt plies, sidewalls and tread bands. As depicted in the following illustration,

26 ETRMA statistics 2019 https://www.etrma.org/wp-content/uploads/2019/10/20191114-Statistics-booklet-2019-Final-for-web.pdf

all these parts are joined in a very precise manner to be submitted to the curing for the obtention of the final tyre article.

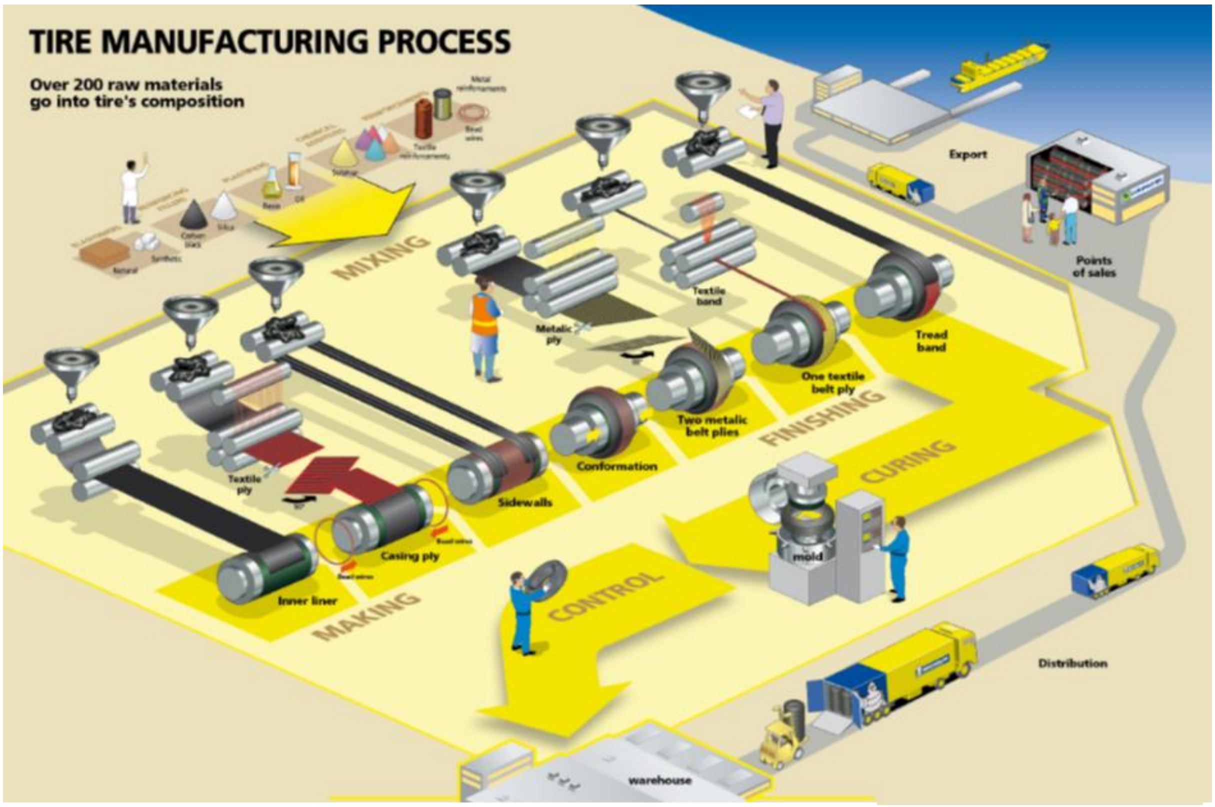

Figure 10: Scheme of Tyre Manufacturing process. Source: ETRMA.

Table 4: examples of the functions of FP-coatings in different applications necessary to manufacture tyres.

Product	Functions of the product in the tyre manufacturing process	Functions of FP-coatings	Field of application
1) Mould	Moulding, curing and demoulding the tyre. Giving the tyre its final shape and surface aspect **Mandatory to obtain given tread sculptures, themselves necessary to reach critical performances, such as wet grip, rolling resistance and noise, the three of them being subject to grading classes for passenger car and truck tyres.**	Anti-sticking properties, high-temperature stability and shape integrity, visual aspect.	Mould coatings.
2) Rollers, ferrules, disks,	Shaping and guiding the rubber through the production line.	Anti-sticking properties	Coatings of metallic pieces of manufacturing

<table>
<tr><td>cylinder, presser plate</td><td></td><td></td><td rowspan="3">machines and process tools in contact with green rubber, intrinsically sticky to metal.

Allow the industrial shaping and handling of green rubber mixes without pollution (transfer) which may cause decohesion between rubber layers during tyre use.</td></tr>
<tr><td>3) Tables</td><td>Storing the rubber temporarily in the production line.</td><td>Anti-sticking properties

Sliding properties</td></tr>
<tr><td>4) Knives, blades</td><td>Cutting the rubber (anti-stick + sliding + wear resistance properties).</td><td>Anti-sticking properties

Sliding properties

Wear resistance</td></tr>
<tr><td>5) Guides, sliding parts</td><td>Guiding the rubber throughout the production line.</td><td>Sliding properties</td><td>Pieces (bulk) of production machines

(No contact with rubber)</td></tr>
</table>

2.2.1. Use of fluoropolymers in the tyre manufacturing process

No PFAS is used in the rubber formulations for tyres. Fluoropolymers (generally thermoplastics) are used in some bulk pieces and coatings in contact with rubber during the tyre manufacturing process, to ensure no friction and no sticking during all the steps of the manufacturing process in a plant (rubber compounding, rubber conveying operations, tyre assembly, curing etc.). The most common fluoropolymers used are PTFE (CAS 9002-84-0: Ethene, 1,1,2,2-tetrafluoro-, homopolymer), PFA (Tetrafluoroethylene-Perfluoroalkyl Vinyl Ether Copolymer) and FEP (CAS 25067-11-2: Tetrafluoroethylene-hexafluoropropene copolymer).

As examples, these fluoropolymers pieces or coatings can be found in guides, galley rollers, rolling disks, tables, blades, metallic rolls coating and curing moulds coating. They are essential for the production of rubber compounds and tyres, in particular to ensure proper demoulding of the tyre after the curing step, in order not to damage tread sculptures.

More specifically, for those steps of the production process that require extra anti-sticking properties such as the curing mould itself, in many cases a coated layer of PTFE of a thickness of no more than some µm is required. This layer might be sprayed, but often applied with a vacuum deposition - in controlled conditions in an encapsulated chamber. Despite the thin layer, large technical advantages are achieved with the use coated fluoropolymers such as PTFE, that excels as follows:

- **Durability:** the layer of the coating material defines the ability of the machinery to process hundreds to thousands tires. After the mentioned cycles, the coating reduces its efficiency as, in most cases, this long lasting coating material itself will not wear off. But after several hundred/thousands produced tyres, all compounds in contact with the machinery will stick at the mould which will lead to reduced quality over time. The application of a new coating will then be required.

- **Performance:** The releasing property is of higher quality and durability compared to "traditional" direct application of liquid release agents onto the tyre mold. This is needed due to the fact that the tread compounds have become more and more sticky, and patterns more complex, over the last years.

At present, no substances other than fluoropolymers have been identified that demonstrate the same anti-sticking and anti-friction properties. In particular, there are no alternatives demonstrating the same anti-sticking and anti-friction properties, without polluting the rubber surface. It is an extremely important point, because a tyre is made from a superposition of different green rubber layers, and any presence of such an anti-adhesive polymer on the rubber surface presents a major health and safety risk, as it could provoke a split of the rubber parts during the life of the tyre.

Furthermore, many GRG products are used in the very functioning of tyre production machinery (e.g., rubber O-ring, fluids piping, etc). These machines themselves require rubber products containing various PFAS fluoropolymer components for both their purchase and maintenance. Thus, there is also an indirect impact on the tyre production chain in the event of a total ban on PFAS, with the risk of many tyre production machines malfunctioning and a potential increase of costs.

ETRMA calls for the authorities to consider the usage of machinery coatings in the tyre industry as essential use. Any ban or restriction on fluoropolymers related to these uses would have a remarkably detrimental effect on the manufacturing as well as on performance of the tyres in the EU.

3. Challenges related to the substitution

3.1. Typical innovation process and timing

Research and Development refers to the systematic and investigative processes undertaken by tyre and rubber goods companies to discover, develop, and test new formulations and products. It involves a range of activities, including basic research, regulatory compliance, assessment of safety and environmental impacts, homologation by the customers, testing and validation as well as manufacturing scale-up.

The whole R&D process is a resource-intensive and highly time-consuming process, often taking several years or even decades from initial discovery to final market availability. Success in R&D leads to the introduction of innovative products that innovative products that offer increased performance. For example, innovation in the tyre sector has led to the launch of energy-efficient tyres, which allow to reduce significantly fuel consumption and therefore CO2 emissions.[27, 28]

However, the process also involves challenges such as high costs and uncertainty. To conduct an R&D project aimed to substitute FEP, PTFE, PFA and other fluoropolymers in rubber goods and in tyre manufacturing, all the typical development steps would need to be carried out:

- **R&D** conducted by suppliers (in collaboration with downstream users);
- **Regulatory compliance** (materials must be compliant with applicable regulations and should meet technical requirements);
- **Reformulation / Re-design;**
- **HSE assessment of alternatives** to guarantee they are safer than FP (hazards, quantities used, potential releases);
- **Full-scale tests** (e.g., laboratory formulation studies, including initial and post-ageing characterization tests), and tests of new manufacturing processes (e.g., manufacture of the rubber mix on an industrial mixer and verification of its processing capacity for the manufacture of parts);
- **Internal approval and certification process (validation)** to ensure the alternative does not affect the integrity of the final product (e.g., undermining the safety of passengers);

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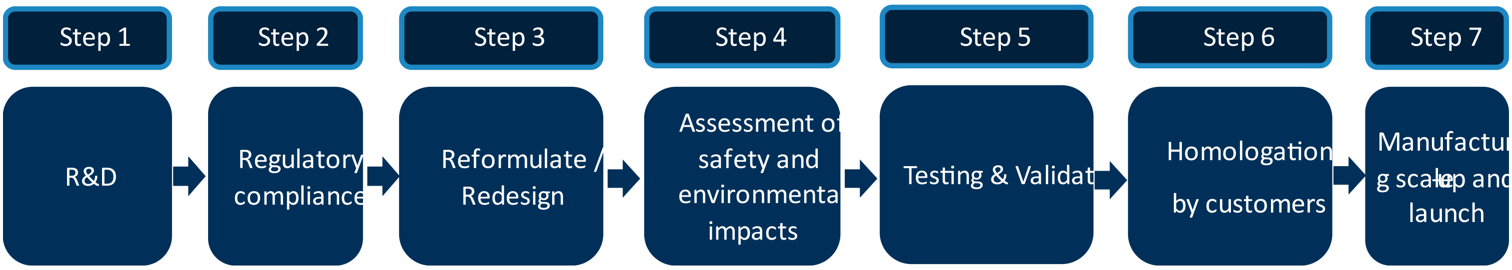
27 See, for example, OECD, 2014. *Nanotechnology and Tyres: Greening Industry and Transport*, OECD Publishing, Paris, https://doi.org/10.1787/9789264209152-en.

28 See, for example, European Commission Consumer's Guide to Energy-Efficient Tyres https://ec.europa.eu/energy/sites/ener/files/documents/FIN%20User%20guide%20-%20tyres.pdf

- **Homologation by customers** (this step is crucial not only for tyres and other components, but – especially – for rubber goods applications in critical sectors such as aerospace, defence, medical devices);
- **Manufacturing scale-up and launch:** Once a new material is tested and validated, the manufacturing stage can start.

The graph below summarises the main steps of the typical innovation cycle in the sector:



<u>From the general availability of a technically feasible alternative, the estimated minimum total development and approval time is 15 years. In other words, not less than 15 years are necessary to complete transition activities (i.e., implementing the substitution of PFAS) from the moment when an alternative is identified, which is not currently the case.</u>

This is only an assumption and review clauses are needed during the R&D phase. It is important to emphasize that as ETRMA member companies are downstream users for PFAS materials, substitution timelines are highly dependent on the ability of the supply chain to offer suitable alternatives. The R&D phase producing potential alternatives to PFAS shall be conducted by suppliers. The key challenge would be the unavailability of suitable materials to address the client's needs. In this regard, the GRG and tyres industry is wholly dependent on the technological progress of their suppliers and has limited impact on efforts to substitute fluoropolymers in these applications.

3.2. In General Rubber Goods

Some applications of rubber goods are requested for aerospace, energy applications, transportation, medical devices, construction, food contact materials and many others to perform in extreme and harsh environments. Most of such applications are either industrial or professional.

Among such applications there are, for instance, rubber seals and O-rings inside motors in aerospace applications, where rubber is in contact with oils at high temperature and extreme pressures. In this case, the O-rings or seals are made of PTFE.

Other example are hoses used in oil and gas industry where working temperature could reach -50ºC degrees in the case of Offshore LPG2 transfer. In this case, the hoses need to be reinforced with a fluoropolymer lining on the outer surface. The use of fluoropolymer-based rubbers is critical for many aerospace, energy, healthcare and automotive applications because of the FP's unique properties.

Those fluoropolymers, typically **FKM** or **PTFE** are chemically, thermally and biologically stable; they do not present significant toxicological concerns and cannot degrade into other PFAS.

The substitutes should have the same combination of properties to be able to perform under the extreme conditions. At the present state of knowledge, there are no other products with equivalent resistance to oil, ozone, external aging and chemicals, which also possess good enough tensile strength, elongation resistance, and DRC.

Substitution efforts

The high price of fluoropolymers already ensures that the use of these materials is minimised by the manufacturers. Fluoropolymers are only used when the unique properties of these materials are really needed.

The industry has replaced fluoropolymers in all applications where suitable alternatives were available and where safety and technical performance are not compromised during the use stage of the products. Fluoropolymers are present in GRG only when the alternatives available don't have enough chemical resistance for the use under harsh and extreme conditions, or compromise safety and performance in critical applications, like aerospace, construction or medical devices.

The combination of properties shown by fluoropolymers make them unique and able to cover a wide range of possibilities/applications, which cannot be achieved by any other material in the rubber industry. Somet other materials could offer similar properties (not the same), but only as concerns one of the multiple properties of fluoroelastomers/fluoropolymers. For example, HNBR/ACM/AEM rubber can offer some resistance to aggressive fluids (but not as broad as FKM), but on the other hand they cannot provide the same level of heat resistance.

Besides ongoing literature review, laboratory trials involving potential substitutes have been under way. Up to now, no alternatives have been found. FKM, PTFE, FEP have always proven superior in chemical resistance to any substitute tested. For instance, as it is impossible to use a hose or seal to transport a chemical if such hose/seal is not resistant to the chemical, substitution was not feasible.

Table 5: Summary of conclusions on alternatives examined.

Potential alternative	Products or product groups examined	Technical feasibility (performance, technical characteristics, etc.)	Economic feasibility
Steel & other metals	Sealing systems, hoses, membranes, O-rings, seals, bearing pads, expansion joints, hoses, other GRG products made with FKM, FFKM, FVMQ, FEPM.	Metals are much heavier: their use would nullify the efforts made to reduce vehicles weight, with negative environmental effects. Their chemical resistance is much lower: in several applications they need to be coated with fluoropolymers. Their flexibility / elasticity is much lower, so they cannot be used in applications where wide and elastic deformations are required. For example, they could not guarantee the absence of leakage, especially where there are strong vibrations, with consequent severe safety problems. Even in applications where they could be theoretically used for this purpose, there would be impossible to disassemble and reassemble the parts (for example, for maintenance), because when they are moved from the initial position, they lose tightness and must be replaced every time. Even more, they cannot be used for components which need to be expanded / deformed / extended, such as membranes in expansion vessels for oil at high temperature, wall in endless piston precision pumps used to dose aggressive chemicals, molten plastics etc., flexible hoses for hot oil, hydrocarbons, aggressive media, steam, etc. They cannot be used where there is friction (and consequent wear), for example in contact with rotating shafts or other rotating parts at high RPMs, especially where metal particles produced by wear can cause materials failure. They cannot be given complex shapes. They cannot be used in applications where thermal conductivity must be avoided.	Where technically feasible, substituting a FP with a metal would require a complete re-design. For seals, higher production costs would be required by seat machining (low Ra are requested to guarantee the sealing). Moreover, maintenance costs would be higher, due to the need to replace metal seals at every inspection. For hoses, production costs would be higher due to precise bending and more complex assembly, in addition to higher assembly costs and higher logistics costs (heavier). Higher operating costs would be moreover needed

			due to higher vehicles weight.
High nickel alloys	O-rings, seals, bearing pads, expansion joints, hoses, mechanical parts, other GRG products.	Same considerations as for metals in general. In particular, nickel alloys are not able to cope with many specific anti-corrosion situations. In fact, those alloys were used for the lining of pumps and seals in the 1970s, however this led to frequent failure of the equipment, resulting in significant challenges in terms of maintenance and safety, related to corrosion and leakage from mechanical seals. Besides, nickel is already subject to many restrictions because it is potentially dangerous for human health.	The same as with metals in general. In particular, the solution would be more expensive, due to low process efficiency, with higher costs, higher maintenance costs, due to more frequent replacement of equipment.
Polypropylene	O-rings, seals, hoses, other GRG products.	Poor chemical and thermal resistance. Worse behavior in food contact applications. Not comparable mechanical properties (rigid, not elastic).	Less expensive, but not suitable
PVC	O-rings, seals, hoses, electrical cables, other GRG products.	Poor chemical and thermal resistance. Worse behaviour in food contact applications. Not comparable mechanical properties (rigid, not elastic), not suitable to produce flexible articles. Soft PVC has low thermal resistance (max 120◦C) and poor chemical inertness (it releases plasticizers when in contact with grease, oil, solvents, hydrocarbons and other chemicals). Poor resistance to degradation by UV and oxygen. In electrical cables, PVC or PE combined with halogen free flame retardants (HFFR) could be considered as a potential alternative in some applications, but not in most industrial applications, where high chemical and thermal resistance, combined with high flexibility, are required. Without fluoropolymers in electric cables, the performance of a wide variety of industrial applications would be seriously downgraded, with lower reliability, higher risks for human health (increased risk of fires) and the environment (increased replacement rates of other plastics, leading to more waste generation).	Cheaper material, but not suitable. In applications where it could potentially replace FP, it would nevertheless lead to higher maintenance costs, due to increased replacement rates.
Glass / Ceramics / Mica	O-rings, seals, bearing pads, expansion joints,	Not suitable for sealings or hoses (no elastic properties, not flexible). As for electric cables, ceramic-based cable insulations may be potentially considered, but these materials would not have the combined set of properties that	Increased maintenance costs.

	hoses, electric cables, other GRG products.	fluoropolymers offer and would not perform under the full set of required situations and process conditions.	
Polyether sulphone	O-rings, seals, bearing pads, expansion joints, hoses, other GRG products.	Not suitable, due to inadequate mechanical properties (not flexible, not elastic) and poor chemical resistance, especially with low-polar organic solvents (ketones and chlorinated hydrocarbons)	Not applicable
Polyimide	O-rings, seals, hoses, electric cables, mechanical parts, other GRG products.	Not suitable in applications where elastic properties are required. Poor chemical resistance (e.g., subject to degradation in hot, humid environments or in presence of seawater). It shows poor resistance to mechanical wear, which proved to be a serious limit in critical applications, such as cabling in aviation sector. In many aircraft models, both fixed wing and rotating wing, short circuits (which led to accidents with loss of lives) were caused by faulty insulation in polyimide-insulated wiring, caused in turn by abrasion, due to vibrations and heat connected to the functioning of the aircraft. That models had to undergo extensive modifications and, in some cases, complete substitution of wires.	Very high costs
EPDM rubber	O-rings, seals, bearing pads, expansion joints, hoses, food contact applications, other GRG products.	Compared to FP, EPDM rubber is much less efficient in terms of temperature and chemical resistance, much less efficient in terms of oil resistance, and much less resistant to abrasion While it could be potentially suitable for some acids and alkalis, chemical resistance is very poor with apolar media (fuels, mineral oils, diester lubricants, etc.). This makes EPDM not adequate, for example, for many sealing applications in the automotive sector, for example in lambda sensors. Considering hoses, it could be used in hoses for medium temperature/aggressive chemical fluids, but resulting in lower resistance, leading to lower durability. In general, the applications where it could be evaluated as alternative to fluoroelastomers are those in which it was previously replaced by fluorelastomers because not performant enough according to new requirements. If used instead of fluoroelastomers in these applications, it will lead to frequent failures. Considering food contact applications, it does not guarantee the same safety standards, due to reduced chemical inertness, cleanability and heat resistance.	Less expensive

Nitrile rubber (NBR)	O-rings, seals, bearing pads, expansion joints, hoses, mechanical parts, food contact applications, other GRG products.	Compared to FP, NBR is much less efficient in terms of temperature resistance, bad in Ozone resistance and exterior aging, in water vapour resistance. Fair to good resistance to hydrocarbons and oils but only at low temperatures (above 120 °C it starts degradating and swelling). Poor oxygen, UV and heat resistance. In several NBR applications, PTFE is added to the compound, in order to obtain permanent low friction performance.	Less expensive
Hydrogenated NBR	O-rings, seals, bearing pads, expansion joints, hoses, mechanical parts.	Compared to FP, HNBR is much less efficient in terms of temperature resistance, and worse in water vapour resistance. Good resistance to automotive service fluids, hydrocarbon-based fluids, but also polar fluids, within the temperature range of −45 to 150◦C for continuous use, but not comparable to fluoroelastomers, who can easily pass 200◦C. Not suitable for contact with acids. Lower resistance to prolonged UV exposure, poor chemical inertness. Poor impermeability. Much higher friction coefficient than FP, thus not suitable for dynamic applications in vehicles. For some applications, PTFE is added to the HNBR compound in order to reduce friction coefficient. It cannot be used in medical and pharmaceutical applications, due to the possible release of acrylonitrile. In food contact applications, its performance is lower in terms of cleanability, chemical inertness, resistance to heat.	Slightly cheaper, but not sufficient availability on the market to replace FP.
Acrylic rubber (ACM)	O-rings, seals, bearing pads, expansion joints, hoses, other GRG products.	Acrylic rubber is less good in high temperature, less good in flexibility. It also has a low tensile strength. Poorer chemical resistance, on average. Good resistance to hydrocarbon and oils but not comparable to fluoroelastomers. Not recommended for polar fluids (coolants, water, etc). Bad impermeability. High friction coefficient.	Less expensive, but not sufficient availability on the market to replace FP.

Ethylene-acrylic (AEM) rubber	O-rings, seals, bearing pads, expansion joints, hoses, other GRG products.	Lower chemical resistance. Good resistance to oil up to 150◦C, but not comparable to fluoroelastomers. Not resistant to hydrocarbon solvents, gasoline and alkali, acids and amines. Poorer low temperature flexibility compared to FVMQ. Bad impermeability. High friction coefficient.	AEM is a specialty elastomer. Global capacities are very limited. The AEM available today barely meets the demand already existing.
Silicone	O-rings, seals, bearing pads, expansion joints, hoses, other GRG products.	compared to FP, silicone rubber has poor mechanical properties (abrasion, cut-through and tear resistance). Limited use at >180 °C, poor dielectric properties, less resistant to hydrocarbons, permeable to gases. In tubing, silicone rubber shows lower temperature and chemical resistance compared to PTFE. In sealings, similarly, the temperature resistance is lower, therefore it is not suitable for the required operating temperature of around 250 °C. Moreover, silicone rubber cannot meet the mechanical properties, such as elongation, required by the automotive sector for critical components. Silicone rubber cannot not perform as well as FKM in food contact applications as far as resistance to oily food is concerned and where hardness is required.	Less expensive, but higher maintenance costs.
PEEK and PI	Use in high performance engines O-rings, seals, tubes	Low performance on leakage i.e., pollutant. Sensitive to concentrated or strongly oxidizing acids. Can be swollen by dichloromethane or dichloro-1,2-ethane.	Very high costs Can contain PTFE.
CSM rubber	O-rings, seals, hoses, other GRG products.	Not feasible, does not achieve desired technical performance.	Not applicable
HDPE	O-rings, seals, tubes, other GRGs used in medicinal products/medical devices	Not compatible with rubber and sterilization processes.	Not assessed
UHMWPE	O-rings, seals, hoses, tubes, other GRGs used in medicinal	Not compatible with rubber and sterilization processes Less resistant at temperature > 70◦C than FP.	Less expensive

	products/medical devices		
PET	O-rings, seals, tubes, other GRGs used in medicinal products/medical devices	Not compatible with rubber and sterilization processes.	Not assessed
Molybdenum Disulphide (MoS2)	PTFE (as low friction additive)	Not suitable for applications with exposure to water vapour or even atmospheric moisture (moisture depletes low friction performances). Not suitable for applications where heavy metal contamination must be avoided, such as food contact applications.	Very expensive
Graphite	PTFE (as low friction additive)	Graphite is electrically and thermally conductive, which could be negative in some applications. Its efficiency is lower, so higher amounts are requested to obtain relevant effects. Finally, the color and the fact it stains could be a problem in some applications.	Not applicable
Boric Acid	PTFE (as thickener / rheology modifier in VMQ compounds)	One of PTFE (powder) applications in rubber sector is as additive in rubber (VMQ) compounds, as rheology modifier, to increase strength of uncured semifinished products (so called green 'strength'). Boric Acid was widely used in the past for this purpose, but it has been replaced by PTFE after being listed in REACH Candidate List for Authorisation because of its reprotoxicity.	Not applicable

Table 6 shows that only fluorinated elastomers can effectively and safely work at temperatures exceeding 180◦C in presence of aggressive fluids while all potential alternatives fail.

Table 6: Key characteristics of potential substitutes in comparison to fluoropolymers.

Material type	T_{max} (°C)	Good fluid resistance	Poor fluid resistance	Purity
NBR	120	Hydrocarbons	Polar solvents, ozone	Low
HNBR	175	Hydrocarbons, ozone		Low
EPDM	150	Water, steam, ozone	Hydrocarbons	Low
VMQ	180	Water, steam, ozone	Hydrocarbons	High
AEM	180	Hydrocarbons, ozones		Low
ACM	170	Hydrocarbons, ozone	Polar solvents, water	Low
CSM	150	Hydrocarbons, water, ozone	Polar solvents	Low
CR	100	Hydrocarbons, water, ozone	Polar solvents	Low
ECO	135	Hydrocarbons, water, ozone	Polar solvents	Low
IIR	110	Water	Hydrocarbons	Low
SBR	100	Water	Hydrocarbons, ozone	Low
NR	80	Water	Hydrocarbons, ozone	Low
FKM	240	Hydrocarbons, steam, sour gases	Amines, polar solvents	Medium to high
FEPM	220	Steam, amines, sour gases	Polar solvents, aromatics	Medium
FFKM	327	All	None	High
FVMQ	200	Water, steam, ozone, hydrocarbons		Medium

One of the problems with the substitution is that search for alternatives must be conducted on a case-by-case basis in collaboration with each specific client. Approval by third parties, e.g., regulatory bodies, is also necessary for some applications. Currently, the industry is already striving to propose alternatives to FP whenever possible, following the client's specifications and conducting lab tests. For instance, to explore alternatives to FP for specific FCM-related uses where fluoropolymers cannot be substituted at the present state of the knowledge, the following steps would be necessary:

- To conduct a literature search on materials that could withstand the conditions imposed by the client's process;
- To verify if a potential alternative is applicable and compliant with the relevant standards in the respective industrial sectors. For example, it should be compliant with FDA requirements and EU 1935/2004 Food Contact Materials Regulation and 10/2011 Regulation for Plastics in Food Contact Materials meaning the material under consideration for a potential substitution must be on the positive list. If not, a request for adding this material to these lists should be submitted, along with a dossier and proof of its safety;

- To formulate and manufacture prototypes;
- To study their chemical and thermal resistance through aging tests in the laboratory;
- To check these prototypes against relevant standards (e.g., FDA requirements, EU regulation 1935/2004, NORSOK M 710 Elastomer Seas standards etc.), based on the sector-specific requirements;
- To provide prototypes to concerned industries for in-situ tests to validate their proper functioning.

The key challenge, however, would be the unavailability of suitable materials to address the client's needs. In this regard, the GRG industry is wholly dependent on the technological progress of its supply chain (i.e., manufacturers of fluoropolymers).

3.2.1. Healthcare Applications

Fluoropolymers are used in healthcare sector when there is a need for safe and resistant mechanical seals, decanters, separators, pumps, tanks, valves, heat exchangers and equipment cleaned using clean-in-place and sterilize-in-place regimes. The key properties are temperature resistance, very good chemical compatibility, biocompatibility, durability and good compatibility with acidic fluids, fatty food products, food grade lubricants and oils. To substitute fluoropolymers, an alternative should combine the same properties. At the present state-of-art, it is unlikely that any alternative, apart from another PFAS, would have similar or superior functions.

Moreover, some of the functionalities of fluoropolymers, which make them preferred alternatives, are the very same that are distinctive characteristics of the PFAS as a group, first of all, persistence and inertness. It follows that any non-PFAS substitute would be less safe, because more likely to interact with human body or a medicinal product.

While there is a 13.5-year derogation for fluoropolymers and perfluoropolyethers for the use in tubes and catheters in medical devices proposed by the Dossier Submitters, it does not cover all critical uses of (per)fluoropolymers in healthcare and, moreover, it disregards the lack of any potential alternatives even remotely comparable to fluoropolymers.

Fluoropolymers, for instance PVDF, are also used in the packaging of medical products, for instance as thin barrier coating on halobutyl rubber stoppers, in particular for syringes and vials. This fluoropolymer coating functions as a barrier preventing migration of substances from the rubber. These coatings are critical for ensuring stability of sensitive injectable medicines (e.g., vaccines, chemotherapy, anti-rheumatics etc.). It is estimated that 20% of all injectables drugs are manufactured with FP- barrier-coated rubber.

There are no alternatives available. Fluorinated polymer films are unique in being extremely inert, meaning they have the lowest possible interaction with medicinal products.

Substitution efforts (packaging)

Uncoated halobutyl formulations have improved dramatically over the last decades, but do not reach the level of performance of the FP coating. Alternative applications, like PET film used as coating or replacement of the halobutyl stopper with TPE, have not been successful either.

For more than 10 years, the manufacturers have been trying to develop a TPE (ThermoPlastic Elastomer)-based stopper, without success. Potentially, TPE might replace fluoropolymers in packaging of some conventional medicinal products, but more sensitive and innovative medicinal products would still require an FP coating.

Even the cleanest rubber formulation now available on the market, after more than 10 years R&D, cannot replace a FP-coated variant.

Table 7: Summary of substitution efforts (all failed).

Potential alternative	Technical feasibility	Economic feasibility
TPE	Failed due to high permeability, chemically not clean enough, not sterilizable.	Not applicable
Next Gen Halobutyl formulation'	Still some unavoidable migrating substances like oligomers, antioxidants and cross-linking side products.	Not applicable
PET-coated	Replacing FP coating with PET coating has been tried, but failed due to low performance compared with FP.	Not applicable

Even if an alternative arises in the future, it will be a long way from an invention to a commercial product, because every change in a medicinal product including primary packaging of a medicinal product (and the coated rubber stopper is a part of primary packaging) needs to be revalidated, resubmitted as a separate dossier and reapproved by a competent regulatory body on the national level.

Once a potential alternative is identified, it will take at least 10 years R&D for a rubber component manufacturer to commercialize it. Then, the pharmaceutical company will need > 4 years for validation.

Assuming there is a viable alternative, both a rubber component manufacturer and a pharmaceutical company need to go through the following steps:

- Screening of potential products;
- Screening of suppliers;
- Qualification (chemical-physical, functional, biological, industrial);
- Manufacturing of Pilot/Industrial batches;
- Manufacturing process validation;
- Stability testing;
- Extractable / Leachable testing.

Once all the qualification data are available, Drug Master File Type III for the packaging manufacturer should be updated, which takes a. 6 months. Then, once all supportive data are available, Pharmaceutical Product Marketing Authorization (Variation dossier) should be updated, which takes from 6 months to 3 years, depending on the market.

3.3. In Tyres manufacturing

PFASs, or, more exactly, fluoropolymers (FP) are utilized in tyre manufacturing for tasks such as moulding, curing, demoulding, and handling uncured rubber mixtures. **Every tyre manufacturing line contains some metallic pieces coated with FP** (from rubber compounding to curing). The locations and quantities of these coated pieces vary depending on the type of rubber formulations processed (and their level of sticking tendency), the tyre type, and the available manufacturing processes, machines, and tools at each plant.

The key functionalities of fluoropolymers lie in their anti-sticking and anti-friction properties (maintained at higher temperatures), complemented by their excellent wear resistance. Therefore, any suitable substitute for these materials must possess these essential characteristics.

The formulations of modern high-performance tyres contain materials that improve the safety performance (for example, braking distance) while lowering the Rolling Resistance (better CO2 footprint) and improved abrasion (prolonging tyre life) thus supporting the Green Deal objectives. Such formulations lead to a high stickiness to metallic surfaces and subsequently also to challenges in manufacturing such as demoulding the tyre from the curing mould for example. The latter becomes especially difficult for the highly complex 3D-shape of modern tyre tread patterns being designed for tyre performance. Furthermore, considering the high curing- and hence, mould temperature, a mould coating using FP is currently used allowing the production of such demanding tyres.

Substitution efforts

As regards FEP, PFA, PTFE and other fluoropolymers used in coatings involved in curing moulds and green rubber processing machines,[29] the following activities to identify potential alternatives have been conducted:

- Literature review
- Laboratory tests in cooperation with formulators and suppliers.

Up to now, no FP-free coatings nor other alternative surface treatments meeting internal requirements of the DUs have been identified.

Table 8: Summary of efforts made.

Potential Alternative	Issues
1) Chromium-based coatings	Surface energy is significantly higher compared to PTFE and therefore it is not suitable for rubber compounds. Solution also considered not relevant due to the presence in Annex XIV Authorisation on chromium VI compounds.

29 'Green' or 'uncured' are technical expressions for non-vulcanized.

2) Silicone-based coatings (including use for green rubber processing)	Not inert; consequently, not feasible, because rubber interacts with coating. Not suitable for green rubber processing, because they induce contamination of rubber compounds due to transfer of molecules of silicone onto the uncured rubber surface, which can lead to safety issues during tyre use.
3) Diamond like carbon coatings (DLC0	Not suitable, because they increase stickiness.

To conduct an R&D project aimed to substitute FEP, PTFE, PFA and other fluoropolymers in tyre manufacturing, the following steps will be critical:

- R&D conducted by suppliers (the product should meet technical requirements)
- HSE assessment of alternatives to guarantee they are safer than FP (hazards, quantities used, potential releases)
- Full-scale tests of the coating applications
- Tests of new manufacturing processes
- Internal approval and certification process to ensure the alternative does not affect the integrity of the tyre undermining the safety of passengers.

Even if the description of lubricants detailed in Annexes of Restriction proposal is not complete, ETRMA considers that uses of fluoropolymers in tyre manufacturing presented in the table above are covered by **the proposed 12-year derogation for 'lubricants where the use takes place under harsh conditions or use is for safe functioning and safety of equipment'.** Nevertheless, 13.5 years (12-year derogation + 18 month of transition period) are clearly not enough to invent, test, and produce a PFAS-free solution for tyre manufacturing and then to implement it.

The overall amounts of FP used in the EU in coatings related to tyre manufacturing might be difficult to assess, because the tyre industry is not a direct customer here, but a downstream user in a long supply chain. However, it is a relatively low amount because of the low coating thickness (100 µm maximum) that has a high impact on manufacturing stability and product performance.

3.4. Conclusions

In **general rubber goods (GRG)** fluoropolymers **have been already substituted where it was feasible**. With fluoropolymers being expensive, they are currently used only in specific critical applications, where the resistance of the GRG to extreme conditions and biosafety are critical. Based on the **current R&D activities, there are no known alternatives for use of fluoropolymers in GRG requested to perform in extreme environments** (oil and gas industry, military) or to ensure high safety level (automotive, aerospace, medical devices and medical applications, Food Contact Materials, construction). To date, the researchers have not been able to identify technically suitable and economically viable alternatives to PFAS in these specific applications.

In **tyre manufacturing applications, there are no known alternatives that are currently available** for uses of polymeric PFAS, or, more precisely, fluoropolymers, where they are used as **lubricants and anti-stick coatings**. Fluoropolymers are critical for manufacturing of tyres due to their unique characteristics, which are broad range temperature resistance, anti-sticking, low coefficient of friction and resistance to wear. To date, the relevant supply chain has not been able to identify technically suitable and economically viable alternatives to fluoropolymers.

Implementing a re-design requires long timelines and converting the entire ETRMA member companies' portfolios implies high costs. As these companies are downstream users for PFAS- based commodities, substitution timelines are highly dependent on the ability of the supply chain to supply adequate information and their capabilities to offer suitable alternatives. Timelines are difficult to predict and highly subject to uncertainty. **The whole process of identifying suitable alternatives could take many years**.

From the general availability of a technically feasible alternative, ETRMA member companies estimated that not less than 15 years are necessary to complete transition activities (i.e., implementing the substitution of PFAS) from the moment when an alternative is identified, which is not the case. As a relatively low amount of FP (compared to negative impacts of a FP restriction on the European economy) is involved, and these FPs are handled in industrial and professional settings, a time-unlimited derogation for these applications will be reasonable.

4. Socio-Economic Impacts

The sections below provide a general overview of the social and economic impacts, considering business impacts for rubber goods industry and the tyre manufacturing process, market impacts (on the product market), and broader EU macroeconomic consequences resulting from a potential REACH restriction of PFAS.

The results of the survey show that the total monetized impact of a non-derogation is estimated to 1.4 billion EUR, including:

- the total economic impact in the EEA: > 404 million EUR;
- the social costs of unemployment would be equal to > 1 billion EUR.

This is only a preliminary overview of the impacts. ETRMA is conducting a full-fledged Socio-Economic Analysis that will be submitted later in the process.

4.1. Economic and social impacts from unemployment

The use of fluoropolymers is reserved to special applications as fluoropolymers do not have economic advantages and are replaced for cheaper solutions when possible. However, for key applications where performance is required for chemical and temperature resistance, fluoropolymers are key to secure safety and efficiency. Rubber articles, including those containing fluoropolymers, are used for the most part – with the exception of a few exceptions such as bearing pads – in more complex systems and machinery such as automotive, aerospace, industrial, to name but a few.

The use of fluoropolymers is thus unavoidable. As shown in the previous sections, to date there are not chemical, nor technical alternatives that can reduce or substitute the amounts of fluoropolymers used in rubber goods.

It is common that services agreements across suppliers of general rubber goods and producers of final articles include provision to producers the same article over a period of time in order to secure replacements of damage pieces. The cycles of service requirements agreed across industry could vary, but it is common to have those agreements on producing the parts of over years (e.g., 20 years in the extreme case of aircrafts). This includes requirements to deliver the very same rubber article under specific technical and chemical compositions. The strict requirements aim, above all, to secure safety, performance and avoid disturbances.

In the event that a chemical alternative is available for fluoropolymers – currently this is not the case – testing and approval could take more than 10 years. The time of development and approval varies across articles. However, the specific technical performance of the current uses of fluoroelastomers make testing, research and development process demanding, detailed and extended in time (see Section 3.1. for details on substitution timelines).

A restriction that limits in time the use of fluoropolymers will not boost substitution, rather place industry and the network created in Europe for highly performant rubber goods under stress and induce disturbances and distrust. Therefore, ETRMA calls for a time-unlimited derogation for fluoropolymers, and envisages risk management measures on waste management that secures due care of waste containing rubber goods with fluoropolymers.

The above request is founded on the high disproportionality of the measure: **a potential broad restriction without derogation for general rubber goods would have disproportionate socio-economic implications on the EEA tyre & rubber sector.**

The companies emphasized that a PFAS restriction would be a serious blow to European production. Several seals product ranges for internal combustion engine applications, high-temperature bearings in the automotive industry, aeronautical applications, and food contact applications would be discontinued, leading to the closure of respective production lines. The process of qualifying substitute products for these applications is time-consuming, spanning years, if not decades, and there is a concrete risk of relocating production to non-EEA countries within this time frame.

Qualifications are very long and very complex. Time depends on the availability of a product with equivalent performance developed by suppliers. Nevertheless, manufacturers indicated that it would be extremely difficult, if not impossible, to re-enter the market even if in the future alternatives to FPs are qualified and used, since many of the products are used in critical strategic applications where safety and performance cannot be compromised.

As a consequence, there would be a considerable impact on manufacturing, supply and sales of these products in the EEA. For example, **the expected income generated through the sales of rubber good products in 2027** (year of the entry into force of the proposed restriction plus 18 months of transition period) **likely to be affected by a REACH restriction of PFAS is estimated at > 449 million EUR/year** (rounded).

In terms of sales volumes, this corresponds to > 1.6 billion units/year that would be impacted by the restriction, including, for example, vibration damping parts, static seals for internal combustion engines, gaskets for car electronics, sanitary thermostat seals, seals for multi-way valves, seals for civil and military nuclear applications, gaskets for various industries, nuclear, defence, as well as thermoplastic parts and gaskets for valve sealing systems.

The direct cost of a PFAS restriction for tyre and rubber goods manufacturers (ETRMA member companies) is represented by the loss of the contribution to the EEA economy of the sectoral Gross Value Added (GVA) generated by EEA tyre & rubber sector. The relevant economic measure to quantify this economic impact is given by the loss of Earnings Before Interest and Taxes (EBIT) generated by manufacturers.

The analysis suggests that, as a result of the proposed restriction, **the sector's total contribution to GVA in the EEA, would lose approximately > 87 million EUR/year, when compared to the baseline scenario** (i.e., assuming no PFAS restriction).[30]

[30] The companies who participated to the survey were asked to project lost sales and EBIT under the assumption that a PFAS restriction were to be fully adopted as of 2027.

Over four years (the time period suggested by SEAC when there is no suitable alternative available in general),[31] the total economic impact amounts to approximately **> 323 million EUR** (NPV, 3% d.r.) for participating companies.[32]

As mentioned before, the survey does not cover the whole EEA tyre & rubber goods market. The market share covered by this survey represents approximately 80% of the whole EEA market for tyres and GRGs. One can use the market share of the manufacturer companies which participated to the survey to extrapolate **the total economic impact in the EEA: > 404 million EUR** (rounded).[33]

As a result of a highly conservative approach, these figures result in an underestimation of the impact and should be considered as a minimum (lower boundary) of the expected impacts of a restriction in the EEA electromagnetic actuators, valves, and sensors that are used in the transportation industry's supply chain.

With the loss of business in the EEA, action would be deemed necessary to reduce workforce, especially EU operations (i.e., production and sales workforce). Consequently, a PFAS restriction would very likely lead to unemployment within the participating companies.

In general, it is difficult to estimate the unemployment because there are several drivers at play, including whether transition can retain the same precise product specifications and reliability performance, if the end user market can be addressed in the future with products that do not rely on PFAS, the time to re-enter the market.

It is estimated that > 5,220 employees directly involved in the manufacturing and supply chain of PFAS based products will face layoff in the EEA. This is equal to 65% of the EEA based workforce of the participating companies. Here we report the monetization of the likely social costs of unemployment for these workers.

The social costs of unemployment would be equal to > 772 million EUR (see details of the calculation in Annex I below). Although companies along the supply chain would face a reduction in sales over the years, we assume for simplicity that the entire workforce will continue working for the other three years. Therefore, one discounts the monetised impact derived above by three years due to the assumed delay in the lay-off, using discount rate of 3% per year, as follows: 772 million EUR x $(1 + 0.03)^{-3}$ = 706 million EUR (rounded). Further details of the calculation can be found in Annex I.

Once again, we can use the market share to extrapolate the total social impact of the unemployment in the EEA. **At the level of tyres and GRG manufacturers, the total impact from unemployment in the EEA caused by a restriction of PFAS is estimated at > 1 billion EUR.**

Other workers would be likely impacted, even though the participating companies are not in a position today to quantify the unemployment effect. Due to the impact on turnover, R&D capabilities would be reduced as well, since the R&D budget is a rather fixed percentage of sales and will not be increased because of the restriction, but the contrary will happen also in terms of employment.

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[31] The time period suggested by SEAC when there is no suitable alternative available in general (SAGA).

[32] Total over four years is calculated using the Excel function =PV(3%,4,-87000000,0,0).

[33] Result of the extrapolation: 323 EUR / 80% = 403.75 million EUR.

Moreover, as a progressive result and due to the expected reduction in sales**, job creation is also expected to be negatively affected**. Manufacturers anticipated that eventually they would inevitably reduce new recruitment.

Accordingly, the economic fallout of a broad REACH restriction of PFAS in the EEA tyre & rubber goods sector would be therefore equal to > 1.4 billion EUR.[34]

Because the REACH restrictions would affect equally the whole EEA industry, the corresponding loss in value added (i.e., loss in EBIT) and the social impacts can be considered as a lower bound estimate of the net impact (EEA industry-wide impact).[35] It does not include the high costs to identify and establish an alternative for the suppliers and the overall industry, which are estimated in the same order of magnitude.

Moreover, it ought to be highlighted that a PFAS restriction would also entail a whole range of indirect costs for companies. For example, the risk of losing other markets in the event of rationalization of the customer's supplier panel, a loss of profitability of the structure through under-utilization of equipment and structural costs not absorbed by volume, loss of business opportunities, as well as disposal and relocation costs to transfer the manufacturing outside the EEA.

Thus, because of a highly conservative approach, these figures result underestimates of the impact, and should be considered as a minimum (lower boundary) of the expected impacts of a potential restriction downstream in the EEA PFAS supply chain.

4.2. Wider economic impacts

It is also important to consider the wider macroeconomic impacts and consequences on the EU society at large, by focusing on the expected consequences for the EEA market. A restriction of PFAS used in tyre and rubber goods applications would have important impacts on the competitiveness of the EEA markets, on the overall EU trade balance as well as on innovation.

4.2.1. Impact on competitiveness

In the medium to long run, surveyed companies have indicated that their manufacturing activities would likely experience a significant shift from EEA locations to non-EEA locations. This scenario has been depicted as the most likely (and inevitable) option to a restriction of PFAS.

Because REACH Restrictions apply to all producers equally when placing products on the EEA market, **a potential broad restriction of PFAS would disadvantage the EEA-based manufacturing versus non-EEA one**, when they compete on non-EEA markets.

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[34] Sum of the economic and social impacts derived above (> 404 million EUR and 1 billion EUR respectively).

[35] In other words, we are assuming that the companies that may benefit from a negative regulatory outcome for PFAS are competitors based outside the EEA (where the REACH requirements, especially in the manufacturing process, do not apply).

- The restriction will apply equally to EEA and non-EEA producers placing products on the EEA market. However, in the case of articles not containing-PFAS in the end-use product, but with PFAS used in the production process, non-EEA producers will be more competitive compared to EEA ones.
- Non-EEA producers would not be able to continue supplying and placing on the EU markets PFAS-containing products, except if they are PFAS-free. When it comes to non-EEA markets, non-EEA producers would be able to continue using PFAS and supply PFAS-containing products that will be more performant. In that case, this will lead to a loss of competitiveness for EEA suppliers because of the accessibility for certain producers to less controlled markets and the revenue that this would generate for these companies.

Indeed, for GRG and products containing FPs, imports would fall under the restriction and ban in the EEA. **This is a major disadvantage for the level playing field.**

4.2.2. Impact on downstream users

Therefore, **the EEA market for tyre & rubber goods manufacturing would be subject to significant hurdles as compared to the non-EEA market.** Ultimately, the EEA would **face a further loss of competitiveness** compared to the rest of the world, in opposition to the EU strategy to boost domestic industry and cut dependencies on foreign suppliers (i.e., EU industrial strategy for 2030).

In a case of a total restriction on PFAS, the most likely anticipated outcome for downstream users that are highly dependent on rubber products are analysed below.

4.2.2.1. Automotive industry

Rubber products find extensive applications within the automotive industry, spanning from Internal Combustion Engine (ICE) and Electrical Vehicle (EV) systems to various components like drivelines, engine parts, powersports vehicles, and turbochargers. These examples offer a broad overview of how rubber parts and shapes are utilized, though it is worth noting that rubber goods come in various forms and grades, each with unique characteristics and properties.

The automotive sector is a significant driver of employment in Europe, with a total of 13.0 million Europeans engaged in auto-related jobs, both directly and indirectly, constituting 7% of all jobs in the European Union. Furthermore, the automotive industry plays a substantial role within the manufacturing sector, employing 11.5% of the EU's manufacturing workforce, which translates to approximately 3.4 million individuals. In terms of government revenue, motor vehicles contribute substantially, generating €374.6 billion in tax revenue for key European markets[36]. Additionally, the automobile industry contributes positively to the EU's trade balance, with a surplus of €79.5 billion. The industry's turnover represents a significant portion of the EU's GDP, contributing almost 8% to the total. Moreover, the European automotive sector is a major player in innovation, investing a

[36] ACEA, Motor vehicles generate €413 billion in taxes for EU-15, new data shows, 2018. Available at: https://www.acea.auto/press-release/motor-vehicles-generate-e413-billion-in-taxes-for-eu-15-new-data-shows/ (Accessed in August 2023).

substantial €58.8 billion in research and development annually, making it the largest private contributor to innovation in Europe, accounting for 32% of the EU's total R&D expenditure[37].

It is crucial to consider the potential impact of restricting PFAS without granting exemptions for the rubber industry. Such a restriction could pose significant challenges for the EU in achieving its goal of becoming a net-zero economy by 2050, as outlined in the European Green Deal. This ambitious initiative seeks to shift the EU and its Member States toward sustainability, reducing their reliance on fossil fuels.

Batteries play a pivotal role in meeting objectives related to low-emission transportation[38], decarbonized energy production, and digitalization, as emphasized by the European Commission. Recognizing batteries as a strategic value chain, the Commission acknowledges their vital role in facilitating sustainable development, promoting green mobility, supporting clean energy, and advancing climate neutrality, particularly in the transition to electric vehicles.

On a broader scope, the automotive sector heavily relies on various PFAS, such as fluoropolymers, fluorinated gases, and short-chain PFAS, as critical materials downstream. Fluoropolymers serve essential roles in multiple technical components like gaskets, hoses, joints, O-rings, seals, cords, cables, and sleeves. However, the existing proposal fails to recognize any exceptions for these applications[39], even though viable alternatives are scarce and lack the necessary properties to meet the requirements.

Within this context, rubber products in the automotive sector, especially those used in battery applications, play a crucial role in enabling low- or zero-emission vehicles. These products contribute to greenhouse gas reduction and support the transition to a low-carbon economy by offering sustainable energy storage solutions and engineered components for EVs and turbochargers. ETRMA's commitment to sustainability and circularity aligns seamlessly with the goals of the European Green Deal, making ETRMA members key contributors to the shift toward a greener and more sustainable future.

4.2.2.2. Aerospace industry

The EEA plays an essential role in the aerospace technology manufacturing industry due to its dynamic nature. The global demand for aerospace products indirectly fuels the expansion of market opportunities for European aerospace and defense firms within the EEA. In 2019, the combined revenue of the European aerospace and defense sector exceeded 250 billion euros, providing employment for approximately 890,000 individuals in the aerospace and defense sector[40].

Airlines have made commitments to achieve net-zero emissions by 2050, prompting actors in the supply chain to explore more sustainable components and aircraft[41]. The aerospace industry places

[37] ACEA, The EU auto industry accounts for 7% of all jobs, 2022. Available at: https://www.acea.auto/figure/employment-in-eu-automotive-sector/ (Accessed in July 2023).

[38] RECHARGE, 2023. Application for derogations from PFAS REACH restriction for specific uses in batteries – First submission
. Submission number: cb6a7d0a-caa1-42fa-a806-f7410538f8b9.

[39] ECHA13, 4276.

[40] Statista, 2022. European aerospace industry – statistics & facts. Available at: https://www.statista.com/topics/4130/european-aerospace-industry/#topicOverview (Accessed in August 2023).

[41] McKinsey&Company, 2022. A dual approach to decarbonization in aerospace. Available at: https://www.mckinsey.com/industries/aerospace-and-defense/our-insights/future-air-mobility-blog/a-dual-approach-to-decarbonization-in-aerospace (Accessed in August 2023).

significant emphasis on reducing emissions associated with fuel consumption by transitioning to alternative fuels such as battery-electric and hydrogen, while also upgrading aircraft fleets to enhance fuel efficiency.

In this context, rubber products find a wide range of applications within the aerospace sector. Rubber components are utilized in nearly all civil airliners, engines, turboprops, as well as military jets and helicopters currently in operation. It is highly probable that all these aircraft will incorporate at least one type of rubber component subject to the scope of the restriction.

Moreover, the aerospace industry operates under a multitude of standards spanning various countries and continents. Within the European Union, aerospace manufacturing processes are overseen by the European Union Aviation Safety Agency (EASA), which enforces:

- Implementing Rules for the Airworthiness and Environmental Certification of aircraft and related products[42] and;
- Commission Regulation concerning the continuing airworthiness of aircraft and aeronautical products, parts, and appliances, as well as the approval of organizations and personnel involved in these tasks[43].

Aircraft typically adhere to design specifications that remain unchanged for several decades, covering the entire manufacturing lifespan of the aircraft model. Any modifications to these specifications must undergo stringent protocols and gain certification and approval from Original Equipment Manufacturers (OEMs), design owners, and relevant aerospace regulatory agencies. This rigorous process is essential because aircraft operate globally and are subject to different jurisdictions, necessitating adherence to consistent approved standards across countries.

As a result of the PFAS restriction, the aerospace industry would experience significant disruptions, impacting various sectors such as machine shops, engine system manufacturers, and airframe manufacturers. This is due to the industry's reliance on complex global supply chains that are tightly interconnected. Rubber is an essential part of the aerospace value chain, present at every stage. Thus, any restrictions imposed on one part of the supply chain would trigger a chain reaction, ultimately leading to a cease of all downstream supply chains.

Finally, military and defense applications encompass a wide spectrum of technologies spanning air, space, land, and marine domains. These applications encompass various assets, including but not limited to aircraft, tanks, submarines, naval vessels, as well as amphibious and terrestrial vehicles. The specific details of these applications are classified, but they share critical requirements such as robustness, coefficient of friction, electrical resistance, chemical resistance, dimensional stability, and thermal stability.

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[42] (EU) No 748/2012. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1473415871666&uri=CELEX%3A32012R0748 (Accessed in June 2023).

[43] Commission Regulation (EU) No 593/2012 of 5 July 2012 amending Regulation (EC) No 2042/2003. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32012R0593 (Accessed in June 2023).

By 2021, European member states have collectively allocated over 235 billion[44] euros to military spending, equivalent to 1.5% of their GDP[45], underscoring the EU's pivotal role in shaping both national and global military and defense strategies. This willingness to invest in the defense sector is also in line with Ursula von der Leyen, President of the European Commission’s commitment to strengthen European defense industry. In this context, a PFAS restriction would have an impact on every level of the defense industry, from aerospace to landcraft, where rubber components are used in many parts of the value chain. This restriction could therefore jeopardize the efforts of recent years to support a powerful defense industry in line with future strategic challenges.

4.2.2.3. Medical devices and applications

Viable substitutes for fluoropolymers and fluoroelastomers, crucial in industries like pharmaceuticals and medicine, are currently non-existent[46]. Rubber materials are indispensable for applications such as chemically resistant barriers and linings, especially when dealing with substances like phosphoric acid, hydrochloric acid, and silane, as well as in agricultural diesel plants. Banning these fluorine compounds would lead to severe supply shortages in Europe and disrupt operations in critical industries.

In economic terms, for the EEA medical devices industry, such a restriction would result in severe supply shortages across Europe and hinder operations in crucial industries. This shortage could result in major changes and huge increase in costs for public health services.

4.2.2.4. Oil & gas

The petroleum and mining sectors play a vital role in shaping European society, providing essential energy resources critical for economic advancement, efficient transportation, and the overall functioning of modern life, both now and in the foreseeable future[47]. Within the European Union, the energy sector directly employs approximately 1.6 million individuals in various capacities, including extraction, production, and energy distribution, contributing EUR 250 billion in added value to the economy. Europe has also seen significant investments in renewable energy sources, and with a population of around 513 million consumers, the EU's energy market ranks among the world's largest common energy marketplaces[48].

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[44] The World Bank, Military expenditure https://data.worldbank.org/indicator/MS.MIL.XPND.CD?locations=EU

[45] Rounded value of ECB exchange rate on 16 August 2023 (EUR 1 = USD 1.09) based on 257.1 billion USD.

[46] ECHA11, 4258.

[47] OECD, 2011. The Economic Significance of Natural Resources: Key Points for Reformers in Eastern Europe, Caucasus, and Central Asia. Available at: https://www.oecd.org/env/outreach/2011_AB_Economic%20significance%20of%20NR%20in%20EECCA_ENG.pdf (Accessed in June 2023)

[48] International energy agency, 2022. Energy policy review. Available at: https://iea.blob.core.windows.net/assets/ec7cc7e5-f638-431b-ab6e-86f62aa5752b/European_Union_2020_Energy_Policy_Review.pdf (Accessed in August 2023).

For the EEA oil and gas industry, the most likely response of downstream customers to the PFAS restriction will be the ending of oil and gas extraction in high-pressure and high-temperature environments. Without access to rubber perfluoroelastomer parts, oil and gas operations in the EEA would come to a complete halt due to a lack of current viable alternatives.

4.2.2.5. Semiconductors / electronics

In the era of ongoing digital transformation, the chip industry is witnessing the emergence of new markets, playing a vital role in innovative digital revolutions ranging from autonomous vehicles to 5G/6G communications. Simultaneously, established sectors are increasingly relying on semiconductors as digitization becomes a priority, impacting everything from computers to security[49]. Despite holding 10% of the global microchip market[50], the EU faces heavy reliance on external suppliers, a vulnerability exposed by recent shortages. To address these challenges, the European Chips Act seeks to enhance competitiveness, resilience, and technological leadership by mobilizing over 43 billion EUR[51] in investments to prepare for and respond to future supply chain disruptions, highlighting the strategic importance of chips in the digital landscape.

For the EEA semiconductors industry, there would be a potential elimination of all semiconductor manufacturing in the EEA if a feasible alternative is not be found for rubber perfluoroelastomer parts. Moreover, manufacturers will likely cease production and move outside the EEA.

4.2.2.6. Energy applications, including batteries and hydrogen

In line with the objectives of the Green Deal, the battery and hydrogen sectors would be heavily impacted by such a restriction. Fluoropolymers sub-group is widely used in the battery industry, and to this day, no alternatives are available for the use of PTFE and of PVDF in primary Lithium and Lithium-ion technologies[52].

The uses of PFAS containing rubber in the different energy sectors, from batteries to nuclear plants, is wide, making a broad horizontal restriction of several thousands of substances in the case of PFAS, irrespective of their actual risk for society and environment. The consequences for the battery sector would mean that the European Union would no longer be able to develop the sector, jeopardising a sovereign industry that is already in crisis.

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[49] Ciani, A., Nardo, M., The position of the EU in the semiconductor value chain: evidence on trade, foreign acquisitions, and ownership, European Commission, Ispra, 2022, JRC129035. Available at: https://joint-research-centre.ec.europa.eu/system/files/2022-04/JRC129035.pdf (Accessed in August 2023).
[50] European Commission, 2022. European Chips Act. Available at: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-chips-act_en (Accessed in June 2023).
[51] European Union, 2022. European Chips Act Fact Sheet. Available at: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-chips-act_en (Accessed in June 2023).
[52] RECHARGE statement for 2nd Call for Evidence, Recharge Batteries, October 2021. Available at: https://rechargebatteries.org/wp-content/uploads/2022/09/Call-for-Evidence_RECHARGE-_-PFAS-restriction-V1.pdf (Accessed in September 2023).

4.2.2.7. Non-exhaustive list of impacted downstream industries

Furthermore, apart from the key sectors mentioned above, many other industries would be heavily impacted by a PFAS restriction with no derogation for rubber perfluoroelastomer parts, causing considerable damage to the following sectors (non-exhaustive list):

- In 2018, the chemical industry, encompassing pharmaceuticals, rubber, and plastics, contributed a substantial 335 billion EUR in added value, making it the most prominent sector within the manufacturing industry of the EU27[53]. This sector represented a significant 17.7% of the total added value. Furthermore, in terms of employment, the chemical industry ranked as the second-largest sector, providing jobs for 3.4 million people and contributing to 12.3% of manufacturing employment within the EU27[54]. It's important to note that the sector's impact goes beyond direct employment, as it generates a considerably larger number of indirect jobs, potentially reaching up to three times the number created through direct employment. For the EEA chemical processing industry, as a result of the restriction, the CPI would most likely stop their operations. Most of the plants rely on fluoropolymer seals and rubber perfluoroelastomer parts to comply with industry emission requirements. Moreover, manufacturers will likely cease production and move outside the EEA.

- The European sealing Association (ESA) members employ 12,500 people, of which 50% are in the manufacturing. These would all be impacted as a result of the restriction. ESA has over 50 members with a combined turnover of 2.6 billion EUR[55]. In absence of PFAS, these business activities would negatively be impacted. The ESA requested an exemption of fluoropolymers (Fluoroplastic & Fluoroelastomer materials) as they are manufactured using low molecular monomers and short chain intermediates. There is no other chemistry available to replace the performance that Fluoropolymers provide for chemical, thermal, plasma and radioactive resistance as seals. By definition any chemical that could withstand those situations would also be considered persistent.

- According to the French Federation of mechanical engineering industries[56], 600,000 FTEs in employment would be affected by a PFAS restriction. Entire industrial factor is affected, with an aggregate turnover of 146 billion EUR in France. 80% of the turnover is expected to be impacted because of the restriction.

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[53] Cefic, 2023. Our contribution to EU27 industry. Available at: https://cefic.org/a-pillar-of-the-european-economy/facts-and-figures-of-the-european-chemical-industry/our-contribution-to-eu-industry/#h-chemicals-is-the-leading-sector-accounting-for-17-7-of-eu27-manufacturing-added-value (Accessed in June 2023),

[54] Eurostat, 2023. Production and international trade in chemicals. Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Production_and_international_trade_in_chemicals (Accessed in June 2023).

[55] https://www.esaknowledgebase.com/wp-content/uploads/2022/03/ESA-Position-Statement-on-proposed-PFAS-regulation-March-2022-1.pdf

[56] ECHA32, 6203

4.2.3. Impact on EU trade balance:

A broad restriction of PFAS would also disadvantage European companies in their trade with the rest of the world. The EEA industry will lose competitiveness on international markets, where they will compete with producers who can continue using fluoropolymers and offer more performing products.

On the other hand, imports of products that do not directly contain PFAS (but are manufactured using equipment containing PFAS, for example) are expected to become more important. Therefore, the EEA market is expected to source these products from outside of the EEA.

As a result, the **overall EEA trade balance would be adversely impacted by the restriction**. A restriction will increase the technological and manufacturing dependency of the EU on foreign countries.

4.2.4. Impact on innovation:

With the loss of business, under the assumption that the percentage of R&D spending in terms of revenue spending remains the same, then a PFAS restriction will also lead to reduced investments in R&D.

More generally, **broad regulatory restrictions, such as the PFAS restriction proposal, have a negative impact on the attractiveness of the EEA for investment**, including investments in innovation and R&D.

Every high tech/high purity industry relies on fluoropolymers in industrial use. Even with a time-limited derogation, both investors (looking at long term investments in plant lifetimes of 15-25 years) as well as manufacturers or importers of fluoropolymers will probably turn away from the EEA market with immediate effect.

Typically, innovation is made for global markets, including EEA, and not for specific regions. The Return on investment (ROI) for research and innovation around non-PFAS rubber products for EEA only is rather limited and the development costs expensive, lengthy and complex for one single region. **A ban on polymeric PFAS chemicals would severely impact R&D activities in the EEA. The EEA risks to jeopardize an important field of innovation.**

The EEA risks as well to lose in technological development. The UK has already excluded fluoropolymers from their PFAS restriction, which means that if the EU/EEA approves the PFAS use restriction proposal with the actual time limited derogations, components made of fluoropolymers for critical strategic applications will not be available for use in the EEA, while still available in the rest of the world.

Conclusion

This Impact Assessment report identifies the main potential negative consequences that the EU society at large would face in the framework of the non-derogation for fluoropolymers used in GRG and tyre productions process. It has been performed in line with existing ECHA guidance under regulatory processes (REACH), in a spirit of methodological coherence. The results are based on a survey focused on the EU industry, with **market share coverage of approximately 80% of the EU market**. It therefore provided sufficiently reliable data for a representative extrapolation of the EU market.

ETRMA member companies support the phase-out of the use of PFAS wherever this is possible. This, however, requires the availability of technically and economically viable alternatives which are to date not readily available. Finding alternatives is not guaranteed, and substitution (if possible) is a time-consuming process due to the complexity of the affected products. This cannot be achieved in the proposed 18-month transition time.

Overall, **the results of the IA can reasonably justify a time-unlimited derogation of polymeric PFAS chemicals used in rubber goods applications and the tyre manufacturing process**, on the grounds that a non-derogation would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment.

It is shown that there are currently **no suitable alternatives to the polymeric PFAS chemicals on the EEA market for use in rubber goods and tyre manufacturing process.** Developing a substitute for PFAS within 18 months is not considered as a commercially viable option for market operators due to excessively long timelines and high costs.

The total monetized impact of a non-derogation is estimated to **1.4 billion EUR**, including:

- **the total economic impact in the EEA: > 404 million EUR**
- **the social costs of unemployment would be equal to > 1 billion EUR.**

The non-derogation also puts at stake some of the political objectives of the European Green Deal, and the transition targets toward a climate-neutral and circular economy. **Tyres and rubber are highly recyclable materials, with a well-established and organized circular economy industry**. It would also be a loss of sovereignty for an industry in which the European Union is a world leader, going against the 2030 strategy of industrial sovereignty.

Annex I – Social impacts

In this section, we report the monetization of the likely social costs of unemployment for these workers.

A well-known guideline in monetizing the social impact of unemployment has been developed by the European Chemicals Agency (ECHA) for evaluating such impact in different regulatory processes. Estimates have been made in accordance with the ECHA document on the evaluation of unemployment (SEAC/32/2016/04)[57] and the paper of Dubourg (2016)[58] endorsed by ECHA. Therefore:

- The average annual salaries across these European workers (including the employer's social security contributions) are assumed to be 60,000 EUR.
- Using Table A7 (column G, considering the gross wages including the employer's social security contributions) in Dubourg's paper, the total social cost of unemployment in Europe is equal to 2.16 times the annual gross salary.
- Table 9 present the statistics from Eurostat (data for 2022-Q4) on the average duration of unemployment for both men and women between the ages of 15-64 years in the EU-27.[59]

Table 9. Duration of unemployment

Duration Grouping	Thousand units	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	1717.6	0.132975141	0.5	0.066487570
From 1 to 2 months	2658.0	0.205780114	1.5	0.308670171
From 3 to 5 months	2013.9	0.155914436	4.5	0.701614964
From 6 to 11 months	1779.0	0.137728677	8.5	1.170693753
From 12 to 17 months	1352.4	0.104701665	14.5	1.518174147
From 18 to 23 months	602.5	0.046645041	20.5	0.956223339
From 24 to 47 months	1459.7	0.113008741	35.5	4.011810292
48 months or over	1333.6	0.103246185	48	4.955816888
Total	12916.7	1		**13.689491124**

The social costs of unemployment for workers would therefore be equal to:

57 ECHA (2016). The Social Cost of Unemployment. Available at: https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

58 Richard Dubourg, 2016. Valuing the Social Costs of Job Losses in Applications for Authorization. The Economics Interface Limited.

59 Data extracted from: https://ec.europa.eu/eurostat/web/products-datasets/-/lfsq_ugad

60,000 EUR x 5,220 FTEs x 2.16 x 13.689491124/12 = 772 million EUR (rounded).

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