ASSOGOMMA
FEDERAZIONE GOMMA PLASTICA

Assogomma comments on the Annex XV Dossier of the universal PFAS restriction proposal

September, 6th 2023

1 About Assogomma

Assogomma is the Italian Association among manufacturers of rubber articles, electric cables and other similar products, established in 1945.

Assogomma represents about 200 firms, a total production of about 550.000 ton, a turnover of about 5 bilion euro and about 25.000 employees (Italy). It is a sector strongly exportation-oriented (about 80%). Complementary economic operators (e.g. providers) are Assogomma members as well.

2 Abstract

The italian rubber industry shares the objective to address the concerns related to the use of PFASs, even adopting a precautionary approach. We nevertheless propose some observations concerning the approach adopted in the restriction proposal.

In fact the scope of the restriction proposal coincides with the whole class of PFASs, which is a very large and heterogeneous group of chemicals, with a very wide range of chemico-physical and eco-toxicological properties. PFASs class is in fact defined based on a very simple structural similarity criterion: using it for the definition of the restriction scope is a simplistic approach which would indiscriminately and unjustifiably target also non-hazardous materials such as fluoroelastomers.

Chemicals should be targeted according to their potential concern, which needs the evaluation of several aspects and cannot be based on just one single structural element.

Fluoroelastomers are safe materials, with unique properties that make them irreplaceable in a series of technological applications, 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.

The concerns related to their life cycle are linked to the use of fluorinated surfactants during the production phase. This problem has been targeted in last years through improvements of risk management measures but further action is indeed required. Ongoing R&D efforts are aimed at the development of alternative technologies, which do not require fluorinated polymerization aids, with promising results.

Fluoroelastomers, and in general fluoropolymers, should be excluded from the scope of the restriction. Remaining concerns related to the use of fluorinated

polymerization aids should instead be addressed through regulatory actions.

3 General observations on the restriction proposal

3.1 Critical analysis of restriction scope

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 [12], 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 [4].

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.

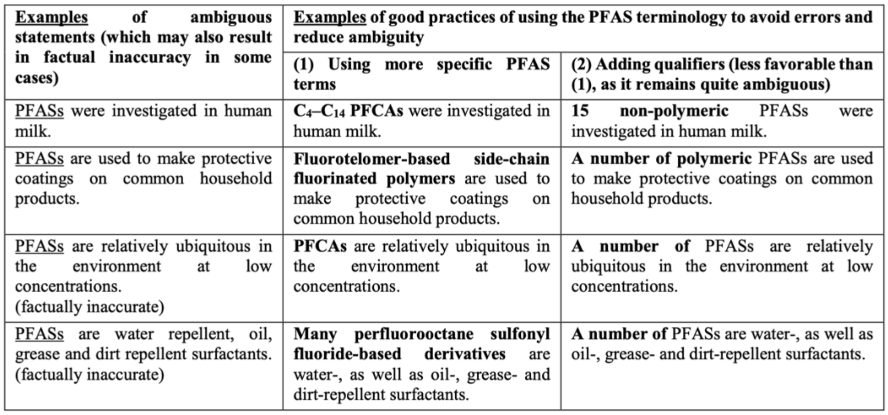
As underlined by the Authors: [12]

1. 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."

2. 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, as some common examples reported in table 1 show.

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. [12]



Examples of ambiguous statements (which may also result in factual inaccuracy in some cases)	**Examples of good practices of using the PFAS terminology to avoid errors and reduce ambiguity**	
	(1) Using more specific PFAS terms	**(2) Adding qualifiers (less favorable than (1), as it remains quite ambiguous)**
PFASs were investigated in human milk.	**C_4–C_{14} PFCAs** were investigated in human milk.	**15 non-polymeric** PFASs were investigated in human milk.
PFASs are used to make protective coatings on common household products.	**Fluorotelomer-based side-chain fluorinated polymers** are used to make protective coatings on common household products.	**A number of polymeric** PFASs are used to make protective coatings on common household products.
PFASs are relatively ubiquitous in the environment at low concentrations. (factually inaccurate)	**PFCAs** are relatively ubiquitous in the environment at low concentrations.	**A number of** PFASs are relatively ubiquitous in the environment at low concentrations.
PFASs are water repellent, oil, grease and dirt repellent surfactants. (factually inaccurate)	**Many perfluorooctane sulfonyl fluoride-based derivatives** are water-, as well as oil-, grease- and dirt-repellent surfactants.	**A number of** PFASs are water-, as well as oil-, grease- and dirt-repellent surfactants.

Table 1: Examples of ambiguous statements and associated good practices of using more specific PFAS terminology to refine these statements[12]

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 [5] and a viewpoint article [13].

However persistence alone is not necessarily an hazard *per se* and in fact in REACH 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 [3].

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 [11]. These phenomena require a relative low molecular weight (in 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).

3.2 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 focussed on the real issues, avoiding an indiscriminate approach, which would unjustifiably deprive European society of many technologies, key for the realisation of plans considered strategic like digital and "green" transitions.

3.3 Focus on fluoroelastomers

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

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

Moreover fluoropolymers are particularly stable from the thermal, biological and chemical points of view and they don't degrade under intended use conditions. They cannot penetrate cell membranes and cannot bioaccumulate.

In a recent study by Korzeniowski et al. [9] it was demonstrated for a series of fluoropolymers available on the market, fluoroelastomers included, that they fulfil the *Polymer of Low Concern* (PLC) definition. The study integrates and supplements an earlier paper by Henry et al. [8].

The assessment took into consideration several aspects, including weight percentage of low molecular weight fractions and impurities, such as monomers, oligomers, processing aids, and their leaching tendency.

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

3.3.1 Use phase

The assessment drawing to the conclusion that fluoropolymers are *Polymers of Low Concern*[9] allows to assume that no significant amount of non-polymeric PFAS are 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 in general mobility of medium-low molecular weight substances present in the material.

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

3.3.2 Manufacturing phase

As expressed in section 3.2, the main issue 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 [9].

Based on these numbers and considering an estimated global fluoropolymers production of $\sim 4 \times 10^5 t/y$ in 2022, it is possible to estimate a fluorosurfactants environment emission of less than $\sim 150t/y$. Focussing on FKM fluoroelastomers (about 15% of total fluoropolymers production [10]), emission can be estimated in less than $\sim 20t/y$.

Moreover R&D projects are being carried out by some major manufacturers with the aim of replacing fluorinated PAs with non-fluorinated PAs, or without the use of any processing aid.

Some preliminary results show that fluoropolymers obtained making use of non-fluorosurfactant technologies, without the use of any surfactant, shows undetectable (LOQ = 1.0 ng/g) content of perfluoroalkylcarboxylic acids and perfluoroalkanesulfonates (see tables 2 and 3). 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

	Perfluoroalkylcarboxylic acids (ng/g)										
smp.	PFBA	PFPeA	PFHxA	PFHpA	PFOA	PFNA	PFDA	PFUnDA	PFDoDA	PFTrDA	PFTeDA
1	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0
2	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0
3	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0
4	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0

Table 2: Quantification results (LC-MS/MS) of perfluoroalkylcarboxylic acids (from PFBA to PFTeDA) in a fluoropolymer manufactured with non-fluorosurfactant technology (Kind permission of Solvay).

	Perfluoroalkanesulfonates (ng/g)							
smp.	PFBS	PFPeS	PFHxS	PFHpS	PFOS	PFNS	PFDS	PFDoS
1	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0
2	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0
3	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0
4	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0	<1,0

Table 3: Quantification results (LC-MS/MS) of perfluoroalkanesulfonates (from PFBS to PFDS and PFDoS) in a fluoropolymer manufactured with non-fluorosurfactant technology (Kind permission of Solvay).

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 our 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.

3.3.3 End-of-life

According to a recent End-of-life (EOL) analysis performed by Conversio [6], 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 ($\simeq 3\%$).

The possible formation of PFAS (short chain or long chain) during incineration of fluoropolymers was investigated in a peer-reviewed study published in Chemosphere [1]. 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) [7], 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 CF_4 or C_2F_6.

Concluding this section, meeting the OECD PFAS definition, which includes a huge number of substances with very different properties, is not a sufficient condition for a substance to be considered hazardous. In particular fluoroelastomers - and in general fluoropolymers - constitute, among PFASs, a subset of non-hazardous substances, which *should be excluded from the scope of the restriction.*

This evidence-based approach has been recently adopted by UK HSE, which, in the RMOA published in march 2023, considers it appropriate to explicitly exclude fluoroelastomers and in general fluoropolymers from a restriction on PFAS [2].

4 Fluoroelastomers and other fluoropolymers used in rubber sector

In rubber sector only polymeric PFAS are used. Fluoroelastomers, such as FKM and FFKM, and fluorosilicones (FVMQ) are used as main constituent (50% - 95%) of certain kinds of rubber articles. Other fluoropolymers, such as PTFE, 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.

A list of fluoroelastomers and other fluoropolymers used in rubber sector is provided in table 4.

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

Table 4: Fluoroelastomers and other fluoropolymers used in the rubber sector

5 Rubber articles containing fluoroelastomers and market data

Fluoroelastomers are key materials to produce a very large variety of rubber articles, which are used in several downstream sectors as components in complex articles/systems.

They can be grouped as follows:

- **sealing elements** of various sizes and shapes, such as o-rings, gaskets, diaphragms, washers, etc.
- **hoses**
- **mechanical parts**
- "**other**", such as components for fashion sector.

In table 5 a quantification of italian market of rubber articles made of fluoroelastomers or containing fluoropolymers is shown. Figures are derived from a survey among Assogomma members; the total italian market can be estimated in about 5.000 ton. In any case, it is a relatively small, though growing, market in terms of volume, but it has a fundamental role in the technological value chain, since fluoroelastomer components are key for a number of strategical applications, as shown in next sections.

	2021 (ton)	2022 (ton)	Δ(%)
Sealing elements	1.736	1.784	
Hoses	1.099	1.073	
Mechanical parts + other	127	152	
Total	**2.962**	**3.009**	+1,6%

Table 5: Italian market (volumes expressed in ton) of rubber articles made with fluoroelastomers or containing fluoropolymers. The figures are derived from a survey conducted by Assogomma among its members. The total italian market can be estimated in about **5.000 ton**.

6 Application sectors

The global market of fluoroelastomers can be estimated in about $3.5 \times 10^4 t$. Fluoroelastomers-based rubber components are used in several sectors, the main ones being listed above:

Automotive : e.g.: 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.

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 contact with 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.

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

Pharmaceutical : e.g. sealing rings, hoses, 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).

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

For these main application sectors, a rough estimation of the respective market shares is provided in table 6.

Other application sectors are:

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

Sector	**Share**
Automotive	$\simeq 80\%$
Chemical - Oil&Gas	$\simeq 10\%$
Pharmaceutical - Food Contact - Semiconductors - Electronics	$\simeq 10\%$

Table 6: Main technological end-use sectors for fluoroelastomers-based rubber parts.

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

Medical devices : e.g. sealings designed for contact with medical gasses, sealings for sterilization devices, etc.

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

Energy applications, including batteries and hydrogen : e.g. hoses, gaskets used in electrical devices, switches, batteries, electric motrs, 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.

Aviation / Aerospace : electric cable sheathing, o-rings, gaskets, tubes, pipes, hoses and other technical items for aerospace applications.

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 (ex 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.

7 Technological role of fluoroelastomers and other fluoropolymers in rubber sector

7.1 Fluoroelastomers

Fluoroelastomers - and in general fluoropolymers - exhibit a unique combination of properties, which cannot be achieved at the same time by any other material. These properties can be summarized as follows:

- Strong chemical resistance, e.g.:
    - fluids: fuels, lubricants, water, steam, complex chemical mixtures, etc.
    - cleaning and sterilization media: acid, bases, steam, ethylene oxide, etc.
    - different type of gaseous plasma
    - humidity
- High temperature resistance (about $270°C$)
- Fire resistance
- Low permeability to gases and liquids (natural gas, hydrogen, fuels, etc.)
- High purity (low metal content, low levels of leachables/extractables, low particle generation)
- Ability to maintain physical properties tipical of elastomers (such as compression set) in harsh conditions and in a very broad range of temperatures (from about $-40°C$, to about $+270°C$).
- Low friction coefficient
- High electrical resistivity

These properties allow to increase lifetime and reliability of components designed to operate in harsh conditions, which results into increased safety, environmental performance and also sustainability.

Considering their much higher cost, they are chosen in applications where their superior properties are indeed required to meet these targets.

The choice of the material in some cases is operated by the producer of the rubber component, but in many cases the material is explicitly defined in the customer's specifications.

Automotive. For example in the automotive sector the use of different types of FKM for different car components is required by many specifications of car manufacturers (VW, BMW, Mercedes, Stellantis, etc.) or of 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 ever-increasing environmental standards required by the EU agenda. 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, FKMs are key for the reduction of fuel consumption, CO_2 emissions, VOC emissions (from fuel tanks and lines), particulates and NO_x emissions.

FKM are also key 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.

Fluoroelastomers and fluoropolymers are also used in batteries and fuel cells, key components of zero-emissions mobility sustained by EU policies.

Aviation. The use of fluoroelastomers (FKM and FFKM) and fluorosilicones (FVMQ) is even more critical in other means of transportation, such as aircrafts. The reason of their widespread usage in this sector is the unique combination of low temperature sealing ability (for FVMQ and some types of FKM), high temperature stability (O-rings close to the aircraft turbines can exceed $300°C$ especially during take-off) and inertness in fuels, lubricants and hydraulic fluids.

Moreover these materials show an excellent resistance to mechanical wear and for this reason they are used for certain type of cable insulations in aircrafts, substituting polyimide, which, due to poor abrasion resistance caused short circuits and consequent serious accidents.

The use of this materials in this sector is required under a series of specifications, such as US military standards (MIL specs), Aerospace Material Specifications (AMS) established by the Society of Automotive Engineers (SAE), British Ministry of Defence specs (DTD specs), British Defence Standard 02-337, French aerospace standards, such as NFL 17 106, etc..

Natural gas. 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 equipments; specifically the requirements for Classes E1, E2, E3 and E4 (up to 150°C operating temperature) can only be met when using FKM materials. Morevoer 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 and ideal for the very low permeability to gases.

Chemical industry. FKM, FEPM and FFKM seals are widely used in chemical process industry as safety critical 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. 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.).

Alternative energies. Moreover fluoroelastomer seals are also getting more and more attention in the so-called alternative energy business, such as hydrogen storage and transportation due to their low hydrogen permeation rate (FKM showed the lowest hydrogen permeation rate among other types of elastomers, such as EPDM, HNBR, NBR, silicones in tests conducted in high pressure hydrogen at an independent lab) as well as hydrogen manufacturing in electrolysers, due to their combined temperature and chemical resistance.

Considering that 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 (CCUS) - i.e. the so-called blue hydrogen process - the role of fluoroelastomer sealings is even more important, since exploration and exploitation of gas deposits with high concentrations (up to 40%) of H_2S (sour gas) can only be safely conducted when using special types of fluoroelastomer seals.

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. No other sealing material is available to withstand water exposure at such operating temperatures.

Semiconductors industry. Also in the semiconductor industry significant quantities of FKM and FFKM are used. In this sector requirements are defined by single customers specifications, according to their specific process conditions. Fluoropolymers are in fact 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 safety critical 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 enhancements in the electronics technology and therefore increasing digitalization; at the same time, they allow safe and effective operation of the semicon 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.

Food contact applications. FKM and FFKM are also much appreciated 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 equipments, such as pumps, mechanical seals and flanges connecting metal pipes. In fact 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 equipments, that make use of a combination of steam, acids and bases.

Moreover FKM and FFKM are well known for their intrinsic higher level of purity, that is a very low overall migration level, compared to other more conventional elastomers, 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.

The use of fluoroelastomers for food contact applications is foreseen by many regulations for food contact materials, such as the US FDA within the Title 21 of the Code of Federal Regulations (e.g. 177.2600, 177.2400), the Threshold of Regulation (TOR) program, and the Food Contact Notification (FCN) program, which impose acceptance limits. EU member state national regulations are inadequate to discipline the use of fluoroelastomers for these applications, even if industry is often forced to select these materials to achieve the technical industry requirements. Food contact EU harmonized regulation about elastomers is still missing.

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. Fluoropolymers are a key enabler for this; in case of restrictions in the use of fluoropolymers, no sealing material would be available to meet these market needs.

For the same technological reasons described above, FKM and FFKM sealing elements are used in the cosmetic sector and also in the pharmaceutical sector, in plants for the manufacturing of many active substances. To meet the even higher standards of this sector, absence of cytotoxicity is often required, through USP Class VI <87> (in vitro) and <88> (in vivo) testing, which fluoroelastomer compoents can pass.

7.2 Other fluoropolymers

Fluoropolymers can also be used as additives in "traditional" rubber compounds for specific applications, in order to meet certain requirements. For example, PTFE is used as additive in silicone rubber (VMQ) compounds to obtain the necessary green strength, enabling the extrusion of complex shaped, or hollow profile sealings, very important for industrial processes (e.g. glass fiber reinforced resins).

PTFE is also used as surface coating of some rubber articles, in order to:

- reduce the coefficient of friction of finished products;
- improve assembly at customer facilities (giving anti-sticking properties);
- color the surface of articles (this helps in order to avoid cross-contamination, increasing the safety, preventing from using the wrong dimension)
- for certain rubber polymers, such as NBR, improve resistance against some types of fuel.

8 Assessment of alternative materials / solutions

8.1 General considerations

The combination of properties shown by fluoroelastomers, with almost no drawbacks, apart from low cold resistance, make them unique and able to cover a wide range of possibilities / applications, which cannot be reached by any other material in the rubber industry.

In fact other materials could offer similar properties (not the same), but only for one of the multiple features 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.

For these reasons in most applications there are not known alternatives to fluoroelastomers. Only in some cases there could be viable alternatives. For example, in the automotive sector, for diesel hoses, where HC emissions are not so important, HNBR could be considered as an alternative, but for gasoline hoses there are no alternatives.

It has to be considered that in most final applications, the "on-the-paper" potential alternative materials are the formerly used materials that have been replaced by fluoroelastomers. As already expressed, the reason of the replacement was the technological development, which introduced more severe operating conditions in order to meet the latest safety and environmental standards. For example: the ever decreasing CO_2 emission levels imposed by EU legislation, together with durability and low maintenance of engines and other mechanical parts of vehicles.

Replacing fluoroelastomers would therefore mean a tecnnological downgrade, which would necessarily introduce problems in terms of safety and / or durability.

Even if an alternative material was found, which is not the case, the replacement of a fluoroelastomer in an application would require a complete re-evaluation, which would take several years, involving engineering, R&D, production tests, validations, etc..

As for coatings, PTFE is the material with one of the lowest known surface energies, which allows one of the lowest possible friction coefficients. Alternatives include plasma deposited coatings, but apart from higher sensitivity to the substrate, these require significantly more energy, so their environmental benefit is not so evident. For example, PTFE-based coatings may be used to create colored coatings, something that is not possible for plasma deposition, graphite and MoS_2-based coatings, and solely partially available with silicone-based coatings.

8.2 Considerations for single specific materials

- **1 - Steel & other metals**

  Product groups analyzed Sealing systems, hoses, membranes made with FKM, FFKM, FVMQ, FEPM.

  Technical feasibility Metals are much heavier: there 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 used for this purpose, they could not allow to disassemble and reassemble the parts (for example for maintainance), because when they are moved from the initial position, they loose tightness and they must be replaced every time. Even more, they cannot be used for component 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 failure. They cannot be given complex shapes. They can not be used in applications where thermal conductivity must be avoided.

Economic feasibility Where technically feasibile, 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, maintainance 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 weigth.

- **2 - High nickel alloys**

  Product groups analyzed Sealing systems, hoses, mechanical parts.

  Technical feasibility Same general considerations expressed for potential alternative 1 (Steel & other metals). In particular, nickel alloys are not able to cope with every specific anti-corrosion situation. In fact, those alloys were used for the lining of pumps and seals used for the MNB plants 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. It has to be noted that that nickel is already subject to many restrictions because it is potentially dangerous for human health.

  Economic feasibility Same general considerations expressed for potential alternative 1 (Steel & other metals). 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.

- **3 - Polypropylene**

  Product groups analyzed Sealing systems, hoses, mechanical parts.

Technical feasibility Poor chemical and thermal resistance. Worse behaviour in food contact applications. Not comparable mechanical properties (rigid, not elastic).

Economic feasibility Cheaper.

- **4 - PVC**

Product groups analyzed Sealing systems, hoses, mechanical parts, electrical cables.

Technical feasibility 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 alternatives in some applications, but not in many other 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).

Economic feasibility Cheaper material, but not suitable in large part of applications. In applications where it could replace FP, it would nevertheless lead to higher maintenance costs, due to increased replacement rates.

- **5 - Glass / Ceramics / Mica**

Product groups analyzed Hoses/pipes, sealing solutions, electrical cables, mechanical parts.

Technical feasibility Not suitable for sealings or hoses (no elastic properties, not flexible). Considering electric cables, ceramic-based cable insulations may be considered, but these materials would not bring the combined set of properties that fluoropolymers offer and would not perform under the full set of required situations and process conditions, leading to lower reliability, higher risks.

Economic feasibility For cables: increased maintenance costs.

- **6 - Polyether sulphone**

  Product groups analyzed Hoses, mechanical parts, sealing solutions.

  Technical feasibility Not suitable, due to inadequte mechanical properties (not flexible, not elastic) and poor chemical resistance, especially with low-polar organic solvents (ketones and chlorinated hydrocarbons).

  Economic feasibility Cheaper, but not applicable.

- **7 - Polyimide**

  Product groups analyzed Hoses, mechanical parts, sealing solutions, electric cables.

  Technical feasibility 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 lost 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.

  Economic feasibility

- **8 - EPDM rubber**

  Product groups analyzed Sealing solutions, hoses, food contact applications

  Technical feasibility It shows poorer thermal and chemical resistance. Considering this latter aspect, while it could be suitable for some acids and alkalis, chemical resistance is in particular 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 obtaining 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 enough performant 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.

Considering food contact applications, elastomers like EPDM, methyl vinyl silicone rubber (MVQ), or NBR could be considered as alternatives, however their life time is shorter (maximum 20.000 life cycles), drastically reducing the durability of the application is drastically reduced. Moreover, these materials cannot reach the same combination of resistance to chemicals and high temperatures as FP can do. In critical applications in food industry where these properties are needed, using materials other than fluoropolymers would seriously downgrade the performance, with increased risk of food contamination or reduced food quality, with possible health concerns.

Economic feasibility Cheaper.

- **9 - Nitrile rubber (NBR)**

Product groups analyzed Sealing solutions, hoses, mechanical parts, food contact applications

Technical feasibility 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. It could be considered as an alternative for hoses for petroleum products, but in any case, it would show resistance problems with some products with high swelling power. In general, the applications where it could be evaluated as an alternative to fluoroelastomers are those in which it was previously replaced by fluorelastomers, because not enough performant according to new requirements. Therefore its use in those applications is expected to lead to increased failure frequency.

Considering food contact applications, elastomers like EPDM, methyl vinyl silicone rubber (MVQ), or NBR could be considered as alternatives, however their life time is shorter (maximum 20.000 life cycles), drastically reducing the durability of the application is drastically reduced. Moreover, these materials cannot reach the same combination of resistance to chemicals and high temperatures as FP can do. In critical applications in food industry where these properties are needed, using materials other than fluoropolymers would seriously downgrade the performance, with increased risk of food contamination or reduced food quality, with possible health concerns.

Economic feasibility Cheaper.

- **10 - Hydrogenated NBR**

  Product groups analyzed Sealing systems, hoses, mechanical parts

  Technical feasibility 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. In any case not comparable to fluoroelastomers, that can easily pass $200°C$.

  Not suitable for contact with acids. Lower resistance to prolonged UV exposure, poor chemical inertness. Poor impermeability.

  ACM, AEM or HNBR have much higher friction coefficients, which make them not suitable for many dynamic applications in vehicles. For some applications, PTFE is added to the HNBR compound in order to reduce friction coefficient.

  In can be considered as alternative in hoses for petroleum products, but it would have limited resistance to some products with high swelling power and to *very* high temperatures.

  For applications where the highest standards of chemical and thermal resistance are required, for example car engines, fluoroelastomers are currently the only reliable option available on the market.

  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.

Economic feasibility Sligthly cheaper, but not sufficient availability on the market to replace FP.

- **11 - Acrylic rubber**

  Product groups analyzed Seals, hoses

  Technical feasibility Lower temperature resistance. Poorer chemical resistance, on average. Good resistance to hydrocarbons in the range of -40 to $175^{\circ}C$ continuous use. Good resistance to hydrocarbon and oils but not comparable to fluoroelastomers. Not recommended for polar fluids (coolants, water, etc).

  Mechanical properties: poorer low temperature flexibility, compared to FVMQ. Bad impermeability. High friction coefficient.

  Economic feasibility Cheaper, but not sufficient availability on the market to replace FP.

- **12 - Ethylene-acrylic (AEM) rubber**

  Product groups analyzed

  Technical feasibility Lower chemical resistance. Good resistance to oil up to $150^{\circ}C$, not comparable to fluoroelastomers, that can easily pass $200^{\circ}C$; not resistant to hydrocarbon solvents, gasoline and alkali, acids and amines. Poorer low temperature flexibility compared to FVMQ. Bad impermeability. High friction coefficient.

  Economic feasibility Cheaper, but not sufficient availability on the market to replace FP.

- **15 - UHMWPE**

  Product groups analyzed Hoses for strong acids and base at medium temperature

  Technical feasibility Less resistant at temperature $> 70^{\circ}C$ than FP.

  Economic feasibility Cheaper

- **17 - Silicone Rubber (VMQ)**

  Product groups analyzed PTFE tubing, Sealings (automotive), food contact applications

Technical feasibility Considering tubing, silicone rubber shows lower temperature and chemical resistance compared to PTFE.

Considering sealings, similarly the temperature resistance is lower: silicone rubber can operate at maximum temperatures ranging between $150°C$ and $200°C$, 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. With very specific formulations, it is possible to increase the temperature resistance of the compound till to $300°C$ (peak temperature), but only suppressing other properties, such as elasticity, hardness, etc. .

Silicone rubber may be a good alternative to FKM for food contact applications, as far as thermal resistance is concerned, but it may not perform the say way as FKM as far as resistance to oily food is concerned. In addition silicone rubber, being softer than FKM, could not be the proper solution in applications where hardness is required.

Economic feasibility The cost of the material is lower, but higher maintenance costs (due to more frequent replacement of the components) have to be taken into account, together with higer waste production.

- **22 - Molybdenum Disulphide (MoS_2)**

  Product groups analyzed PTFE (as low friction additive)

  Technical feasibility Resistant to high temperatures and suitable for lubrication in high vacuum applications, but not suitable for applications with exposure to water vapour or even atmospheric moisture (moisture depletes low friction performances of MoS_2). R&D sctivities are ongoing to improve MoS_2 performances in some applications and the best option seems to be substitution with PTFE. MoS_2 may not be suitable for applications were heavy metal contamination has to be avoided, such as food contact applications.

  Economic feasibility MoS_2 is about 5 times more expensive than PTFE and it has to be added in higher concentrations in rubber compounds.

- **23 - Graphite**

  Product groups analyzed PTFE (as low friction additive)

Technical feasibility 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.

- **24 - Boric Acid**

  Product groups analyzed PTFE (as thickener / rheology modifier in VMQ compounds)

  Technical feasibility As expressed before, 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.

In table 7 the features of alternative elastomeric materials are summarized and compared to fluoroelastomers. The table shows that no other non-fluorinated elastomer can effectively and safely work at temperatures exceeding $180°C$ in presence of aggressive fluids.

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

Table 7: List of alternative elastomers, with the corresponding main features. Fluoroelastomers features are reported for comparison

9 Conclusions

PFASs constitute a very large class of chemicals, with very different chemico-physical and eco-toxicological properties. Some of these chemicals are a cause of concern and our industry fully shares the need to take appropriate measures for their management.

However a sound approach should be adopted in order to classify molecules according to their potential concern, which needs the evaluation of several aspects and cannot be based on just one single structural element.

Fluoroelastomers, and in general fluoropolymers, constitute a separate group in the large class of PFAS. They are inert and stable materials, insoluble in water, non-mobile, non-bioavailable, non-bioaccumulable and non-toxic.

Remaining concerns are related to the use of fluorinated polymerization aids during their production. Alternative technologies are being developed without the addition of these substances.

Due to their unique combination of properties, fluoroelastomers are used to produce components intended to operate in harsh conditions (such as high temperatures, aggressive chemical environments, or both). Considering their higher cost, compared to other “traditional” elastomers, they are used only when really needed, in order to improve safety and durability and reduce emissions in the environment.

Many of their technological applications are key for the implementation of strategic plans such as the digital and green transitions and no equivalent alternatives are known.

For all these reasons fluoroelastomers, and in general fluoropolymers, should be excluded from the scope of the restriction. Fluorinated polymerization aids should instead be targeted, considering the remaining concerns related to their use.

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