CONFINDUSTRIA

Proposed REACH restriction on PFAS
Comments Confindustria

Position Paper

September 2023

Date - Year

1. Premise

On 7 February 2023, the European Chemicals Agency (ECHA) published the proposed REACH restriction on PFAS.

The proposal was prepared by the authorities of Denmark, Germany, the Netherlands, Norway and Sweden and was submitted to ECHA on 13 January 2023. Its goal is to reduce PFAS emissions into the environment and make products and processes safer for people.

The authorities that prepared the restriction dossier indicated two possible restriction scenarios ("*Restriction Options*", RO). Both restriction scenarios involve banning the production, use and placing on the market of PFAS as substances. In addition, PFAS may not be placed on the market in another substance, as constituents of other substances, in mixtures or in articles above certain concentrations.

In particular, the two restriction scenarios include the following requirements:

- RO1: Total restriction of PFAS with no derogation provided for and a transition period of 18 months;
- RO2: Restriction of PFAS with a number of derogations and conditions.

The conditions proposed under RO2 are as follows:

- transitional period of 18 months for entry into force;
- a series of derogations limited in time (from 5 to 12 years);
- the only unlimited derogations concern active substances in biocidal products, plant protection products and human and veterinary medicinal products;
- anything that does not fall within the two previous cases and not expressly specified in the proposed derogations, will be banned at the end of the transitional period (e.g. food contact material for consumer use, non-stick pans, cosmetics, household products, etc.);

As indicated by the authorities that prepared the restriction dossier, RO2 is considered the most proportionate and balanced scenario (p. 3 PFAS Restriction Report).

A **six-month public consultation was launched on 22 March 2023.**

Given the above, with this document, Confindustria, with the usual collaborative spirit, intends to present its observations on the proposal in question, with the hope that it will be possible to achieve a reconciliation of the worthy interests at stake, through a balancing of the same that also takes into account the technical feasibility of the new provisions covered by the aforementioned proposal.

2. Definition of PFAS

"*Perfluoroalkyl and polyfluoroalkyl substances*", referred to by the acronym **PFAS**, are substances containing one or more fully fluorinated carbon atoms and represent a large and diverse group containing thousands of chemical **compounds with widely diversified physical and chemical properties, health and environmental profiles, uses and benefits. These substances are used in the manufacture of products in many sectors.**

The Organisation for Economic Co-operation and Development (OECD) has published a report, which summarises the work carried out by the OECD/UNEP3 Global Panel PFC2 between June 2018 and March 2021 to revise the terminology of per- and polyfluoroalkyl substances, known by the acronym "PFAS". The aim of the report is to provide recommendations and practical guidance to all stakeholders regarding PFAS terminology. The OECD highlights and emphasizes that the term "PFAS" is broad, general, non-specific, that it does not define whether a compound is harmful or not, but only communicates that the compounds under this term share the characteristic of having one or more carbon atoms completely fluorinated and therefore, strongly recommends that this diversity be adequately recognized and clearly communicated, specific and descriptive by authorities and other interested parties. Furthermore, the report clearly highlights how PFAS have different molecular structures and therefore different physical, chemical and biological properties (e.g. non-volatile or volatile; soluble or insoluble in water; reactive or inert; bioaccumulative or non-bioaccumulative, etc.).

For the purposes of the REACH restriction, the 5 Member States that submitted the dossier according to Annex XV of REACH, applied - net of some exceptions, reported on p.4 of the PFAS Restriction Report - the definition of PFAS given by the OECD: *"Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)",* extending it to all substances derived from PFAS. It is also interesting to underline how the OECD itself indicates that the chemical definition of PFAS provided is not connected to how these compounds should be grouped for regulatory actions, suggesting the risks of using such a broad definition to regulate chemical compounds that have extremely varied chemical-physical and toxicological properties.

Thus, the original OECD definition, which included around 4,700 substances, has been extended to include more than 10,000 substances.

In such a large group restriction, however, the diversity between the molecules that are part of it is not taken into account. Not all PFAS have the same properties and the same environmental and health impact: for example, fluoropolymers have different physical, chemical and toxicological properties from other substances identified as PFAS. In fact, fluoropolymers meet the OECD criteria [1]for Polymer of Low Concern polymers: they are chemically and biologically stable (therefore do not break down into smaller PFAS molecules and are stable in air, water, sunlight, chemical and microbial environments) and non-bioaccumulative (as extremely large molecules).

The basic reason why PFAS have been grouped together is that they have persistent characteristics, which, however, do not amount to posing a risk. The term persistent refers to substances that, once released into the environment, remain unchanged (or stable) for long periods of time. Thanks to their unparalleled durability, in particular, fluoropolymers and perfluoropolyethers can be considered persistent from an environmental point of view but this characteristic makes them critical materials and currently still difficult to replace for products containing them. Fluoropolymers and perfluoropolyethers also do not break down and release potentially harmful chemicals once released into the environment and are not bioavailable. For

1 OECD: "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance" (https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf)

these reasons, fluoropolymers and perfluoropolyethers meet the criteria of *Polymers of Low Concern* and are in fact characterized by a favorable toxicological profile. Moreover, substances that are only persistent – in the absence of further risks – do not meet any criteria defined by European legislation that could justify this proposed restriction.

Just last April, the UK Health and Safety Executive (HSE) published a "*Regulatory Management Option Analysis*" (RMOA) for PFAS under the UK's REACH. This non-binding document will help the UK authorities in regulatory decision-making on PFAS.

The UK's approach appears to be more pragmatic and science-based than the proposed restriction of PFAS that is being discussed at European level. In fact, in the UK document, fluoroplastics and fluoroelastomers are considered low-risk PFAS groups.

In essence, the definition of PFAS considered by the UK is as follows: ***"Fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it) or two or more contiguous perfluorinated methylene methylene groups (-CF2-)."*** The UK Authority has, therefore, adopted a narrower definition of these substances, excluding the criterion that a single isolated methylene group (-CF2-) is sufficient for classification as PFAS. With this definition, the number of PFAS involved in a possible restriction would be very small compared to the 10,000 substances covered by the current European proposal.

The UK Environment Agency, which has worked with the HSE, concluded that certain risk management measures (restrictions) may be appropriate for certain uses of PFAS, such as:

a) use and disposal of fire-fighting foams where non-PFAS alternatives are available;
b) other widely dispersive uses such as the application of coatings or the use of detergents;
c) the manufacture and placing on the market of consumables from which PFAS are likely to be released into air, water, soil or transferred directly to humans.

The same Agency also states that the restrictions should not be applied to types of PFAS or their uses if considered low-risk such as, for example, fluoroplastics or fluoroelastomers, intermediates, uses in sealed/confined systems (including use as heat exchange fluids in heat pumps and refrigeration systems): these cases are covered as derogations.

Instead, it recommends interventions on consumer articles from which PFAS are likely to be released and indicates the UK REACH Authorization regime (Annex XIV REACH) as an appropriate regulatory tool to mitigate the risk related to the use of PFAS used as processing aids in the production and processing of fluorinated polymers. In addition, it looks forward to further assessments and investigations of substances of concern and continued collaboration between different government bodies with external stakeholders.

We believe that, given the lack of information on the danger of some PFAS and the real extent of PFAS use across value chains and downstream sectors, this approach should also be adopted for the EU.

In particular, it is considered that the grouping proposed for the restriction is not scientifically valid, and that a more balanced approach should be adopted, taking into account aspects beyond mere chemical structure. In this regard, while we understand the motivation of the Competent Authority to avoid "regrettable substitution" (replacing a substance with one with similar characteristics of concern), **we believe it is essential that the restriction is**

based on scientific data and on a risk assessment, thus defining a narrower group of substances that is also more easily manageable from the point of view of the restriction.

3. Use of PFAS

Thanks to their significant chemical and thermal stability, PFAS, and the substances and molecules made thanks to their aid**, confer distinctive properties that make possible an extremely varied range of applications**, some even of strategic importance.

Table 1 summarizes, in a non-exhaustive way, some macro-areas where PFAS are used for their distinctive properties.

Table 1 – Non-exhaustive analysis of the uses and added value of PFAS use in the main application areas.

CATEGORY OF USE	SPECIFIC USE
Electrochemical energy generation and storage systems	• **<u>Lithium batteries:</u>** At the level of the electrodes PVDF (Polyvinylidene Fluoride) and PTFE (polytetrafluoroethylene) are used as high-performance binders. Other cell-level uses include coatings, separators, additives in the electrolyte, gaskets and sealants, pipes, valves and gaskets (e.g. FEP and PTFE). Therefore, the elimination of fluoropolymers would also hinder the spread of electric or alternative fuel vehicles, inhibiting the achievement of the Green Deal targets. • **<u>Fuel Cells:</u>** Fuel cell membranes are critical technologies in which fluoropolymers, especially PTFEs in proton-exchange fuel cell membranes (PEMFCs) and hydrogen fuel cells, are not replaceable. • **<u>Flow batteries</u>** Fluoropolymers in vanadium redox flow battery membranes. Ionomer exchange membranes offer an environmentally safe way to generate energy using hydrogen without CO2 emissions
Automotive	Different families of PFAS, belonging to both macro-categories of fluoropolymers and fluorinated gases, are used in motor vehicles.

Fluoropolymers

They are used in a large number of automotive applications because of their properties: resistance to chemical degradation, heat resistance, low friction, mechanical properties, dielectric properties, non-stick, low permeability and durability.

The combination of these properties, present simultaneously in a single material, is the reason why fluoropolymers are used on a large scale in vehicle systems where resistance to different types of stress is required (high temperatures, corrosion, mechanical stress, etc.).

A 1-to-1 replacement with another material that guarantees all these characteristics together at the moment is not feasible.

Therefore, fluoropolymers are present in systems such as:

- feeding;
- engine;
- transmission;
- exhaust gases;
- fuel cells;
- Batteries;
- electrical and electronic system.

And in components such as:

- Sealants;
- hose materials;
- gaskets and coatings;
- liquid crystals and semiconductors;
- Wiring;
- O-ring.

Fluoropolymers, as high-performance, durable and resistant materials, help make the entire vehicle more durable, reliable and performing.

In particular, fluoropolymers are crucial in low-carbon mobility as they enable the use of alternative fuels such as biofuels, but they are also essential for electromobility as key components of innovative batteries and fuel cells.

Refrigerants:

Vehicle air conditioning systems use refrigerant gases such as HFO-1234yf which fall under the definition of PFAS.

These refrigerant gases maximise the energy efficiency of air conditioning systems, ensure the safety of operators and end-users and reduce the environmental impact in terms of CO2 equivalent.

On an existing car, with an air conditioning system fitted, it is not possible to replace the refrigerant present with another gas.

The replacement of the refrigerant in the climate system implies the redesign

	of the entire climate system and the engine compartment and this action is unthinkable on the models already in circulation. Therefore, the restriction of the current refrigerant should only apply to new types of vehicles (new type-approvals) and provide for transitional periods distinguishing between new types of vehicles and new registrations (of existing models), with a further distinction between passenger cars and heavy goods vehicles. **Perfluoropolyethers (PFPE)** Perfluoropolyethers are a particular class of polymeric PFAS, consisting exclusively of carbon, fluorine and oxygen. PFPEs are liquid polymers, mainly used as high-performance lubricants in various industrial sectors, including automotive, aerospace, semiconductor manufacturing, food industry, chemical and energy industry, medical sector. In applications where PFPE is used, they provide performance that is not achievable by other hydrogenated or silicone lubricants, so they are extremely difficult to replace. These lubricating perfluoropolyethers fall under the definition of Polymers of Low Concern and are characterized by a favorable toxicological profile.
Sector Aerospace & Defense	PFAS are essential for the continued operation of Aerospace and Defense products, whose service life is more than 40 years, as well as for the production of new products, spare parts and future technology programs related to product electrification. Any alternative to PFAS must necessarily guarantee performance at least equivalent to that currently ensured by the materials containing them, as well as ensure that the safety and reliability of the product are not compromised. The Aerospace and Defense sector is, in fact, highly regulated and with particularly stringent product-specific requirements and subject to strict contractual, qualification and certification requirements, supervised by regulatory bodies and agencies such as EASA (European Aviation *Safety Agency*) and FAA (*United States Federal Aviation Administration*). The Aerospace and Defense industry depends on PFAS in a wide range of applications due to their fundamental performance properties in extreme operating environments, making them the only choice currently available. Applications in this area include fuselage design and assembly/testing, wing design and manufacturing, engine manufacturing, landing gear, fuel systems, helicopters, carbon fiber reinforced plastic components, internal data and fuel systems; a complete mapping is contained in the dossier that Aerospace and Defence Industries Association (ASD - European Association of the Aerospace and Defense Industry), with the contribution of Italian companies belonging to the National Association (AIAD), will present as part of the Public Consultation on PFAS. The high thermal and chemical resistance, their durability, electrical and insulating performance, non-stick and non-wetting properties offer a series of advantages, including:

<table>
<tr><td></td><td>

Increased security
Improved reliability
Effective and long-lasting protection against heat, UV rays, aggressive fuels, moisture, vibration and compression
Weight reduction

Main applications and uses (details in the dossier presented by ASD):

battery systems;
wiring and electrical systems (displays, connectors, cables, printed cards, relays, ...);
membranes and filtration systems (oil, fuel, air, ...);
hydraulic systems and hydraulic fluids;
valves, gaskets, sensors and actuators;
lubricants;
adhesives, sealants, anti-abrasion/corrosion paints;
air conditioning systems and related gases;
extinguishing systems and related gases;
solvents for precision cleaning;
bearings, bushings;
Composite acoustic panels
In-flight connectivity (electronics)
Pipes and fuel lines
Hydraulic systems
O-rings, gaskets, lubrication
Electronic systems
Coating for a variety of purposes (cables, wires, etc.)
Tapes, wires and cables
Satellites: fluoropolymers can be used as fuel for satellite propulsion systems (solid fuel instead of liquid)
External surface coatings
Protective films for radar systems;
Protective films for satellite optics;
Protective films for guidance systems for independent guided missiles.

</td></tr>
<tr><td>Textile and Tanning Sector</td><td>
They enable textiles to play numerous key roles for society, from protecting essential workers to filtering systems.

Clothing (e.g. jackets, trousers, skirts), gloves, footwear and PPE for outdoor activities (professional and not)
Jackets, trousers, gloves and footwear and PPE for professional use (professional and consumer use), e.g. technical fabrics for firefighters, law enforcement, armed forces, civil protection, professionals in the chemical, petrochemical industry, etc.)
Leather goods (bags, watch straps)

</td></tr>
</table>

	• Aerospace suits • Fabrics with fluoropolymer membranes are a key component for a composting solution for the treatment of organic waste (green waste, food waste, source-separated organic, biosolids or municipal solid waste – MSW) • Industrial filtration and gas sampling for emission prevention in the chemical and energy sectors • Sewing thread, fibers and yarn for weaving and PTFE are used in aggressive environments and high-performance ropes • fabrics for medical applications • Textiles and skins for the home: carpets and carpets, curtains, fabrics and leathers for furnishing • padded for car interior.
Building	Processing aids in the production of construction products, architectural fabrics, paints and coatings, coating additives, superhydrophobic coatings, primers for wood and inks, rust protection systems, marine paints, resins, printing inks and coatings in electrical applications. • Architecture films are used as parts of the roofs of stadiums, domes and other structures • Fluoropolymer-coated glass fabric roofs and laminated coatings • PTFE fabric • "Cool Roof" technology (for energy saving) Fluoropolymers, an essential component of the most advanced coating and insulation applications, provide remarkable resistance to adverse weather conditions, longer building life and therefore greater energy efficiency.
Electrical-Electronic Sector	PFAS-containing materials are critical to the manufacturing infrastructure of microprocessors used in personal, industrial and professional high-tech electronic devices. They help meet the needs of ever-changing design complexity and miniaturization in semiconductors for a wide range of electronic devices and data transfer between these devices. They are also characterized by high chemical inertness, perfect compatibility with food contact, resistance to high temperatures, high pressures, rubbing with high-speed parts, non-stick characteristics and ease of cleaning. Their durability, purity, strength and chemical inertness offer numerous advantages including: • Semiconductor and photovoltaic cell manufacturing infrastructure: pipes, tanks, valves, pumps, spinners, filters, gaskets, fluid storage containers and wafer baskets • Protective films and packaging for printed circuit boards and

	semiconductor parts • Displays, touch screens, smartphones, copier rollers and paper feeders • Anti-drip additives, easy to clean and non-adhesive for computers and other electronic devices • Wires and cables used in a wide range of industries, particularly where reliability in aggressive environments and/or high-volume data transmission (e.g. high voltage cables, medical, data center, automotive, wireless communication) • Wire and cable isolation (Cat 5-7 plenum cabling, USB-C, mobile phone riser cables) • Hard disk drives • Wearables • Components of electrotechnical and electronic equipment: electronic components, ball bearings, hinges, gaskets, hoses, non-stick coatings, compressor oils, etc. • Conformational coatings for protection and insulation of electronic boards • Conformational coatings with UV, moisture and solvent barrier properties • Conformational coatings for elements used in human-driven and independent electric vehicles. The dielectric properties also make PFAS-containing polymers fundamental for the photolithography process for the production of semiconductor devices. Similarly, due to their specific chemical properties, some fluorinated gases, which fall within the definition of PFAS, are necessary for the *etching* and cleaning process of some semiconductor device production reactors. In general, in the semiconductor manufacturing industry, many polymeric PFAS (fluoropolymers and perfluoropolyethers) and non-polymeric PFAS are considered essential materials and difficult to replace.
Renewable energy	Photovoltaic: • Front panels: protected by fluoropolymers, guarantee resistance to atmospheric agents, blocking of ultraviolet rays, optical transparency, fire resistance • Rear panels: improve electrical insulation, weather and chemical protection • Vents: fluoropolymers are used e.g. in junction boxes • The excellent chemical resistance to corrosion and abrasion of fluoropolymers plays an important role in increasing the life of solar panel components thereby reducing failures and interruptions due to maintenance. • Production of polycrystalline silicon or polysilicon. Polysilicon is the key element of the most widespread photovoltaic module technology. PFAS are used for the treatment of polysilicon during the production phase and do not remain in the finished product. As there

	are no alternatives available, the restriction could pose a threat to European production. On the contrary, non-EU production would not be affected by the Restriction. In order to maintain and strengthen this strategic sector in Europe, therefore, a long-term derogation is necessary. • Inverter. Inverters are a crucial component of any photovoltaic system and currently depend on the use of PFAS that make the products waterproof, resistant to chemical aggression and high temperatures. As no alternatives are currently available, a long-term derogation is considered necessary. Heat pumps: Fluoropolymers guarantee the following functionalities during the operation of heat pumps: tightness at high and low pressures / temperatures to prevent the release of refrigerant into the external or internal atmosphere and allow the best efficiencies of the machine; ability to withstand temperature gradients that can reach 200 ° C and pressure differences up to 45-120 bar; extended service life; shrewd operation of the electrical and electronic systems responsible for intervening in emergency situations on the operation of the machine and responsible for continuously monitoring the operating parameters in order to minimize consumption; reduce friction of refrigerant and lubricating oil used within the refrigerant circuit. PFAS are also used in numerous heat pump components, many of which, to our knowledge, do not have an alternative solution available: compressors, vents, coaxial cables, electronics (diodes, compensators), coolants, paints and coatings of the external cabinet, heat exchanger tubes (hydrophilic coating), gaskets, o-rings, PCB coatings, pumps, semiconductors, coatings and wire insulation. Wind turbines: • Control Centers for offshore wind farms and turbine blade manufacturing • Paints and coatings: long-term protection from atmospheric agents to increase product life, extend maintenance cycles • Conformational coatings for rotor shaft protection • Conformational coatings for control/interconnection electronics with the distribution network. Energy storage: used as a component e.g. binders that provide chemical, heat and oxidation resistance and long-term storage of renewable energies and stationary energy storage.
Food industry	• Coating of valves, pipes, pipes, filters, seals, gaskets and other standard components for fluid management • Coating of mixing vessels and tanks

	• Coating on processing belts • Laboratory material • Items that need sterilization • High efficiency dry powder inhaler • Packaging coating, non-stick cookware, industrial applications
Pharmaceuticals	PFAS substances are widely used in the pharmaceutical sector: they can be constituents of the finished product (medicine), they are part of materials and equipment used in pharmaceutical production, R&D and drug quality control, they are present in some primary packaging, excipients and propellants. **Medicinal products containing PFAS**: The presence of the functional group -CF2/-CF3, due to its chemical characteristics, allows to optimize key parameters such as bioavailability, binding affinity with the therapeutic target, elimination by catabolism, giving greater efficacy and safety to medicines. There are more than 300 fluorinated medicines available in Europe and more than 500 are in late-stage clinical trials; Today, about 30% of all pharmaceutical active substances contain fluoride. **Pharmaceutical production**: Fluoropolymers and fluoroelastomers are widely used in plants, equipment and consumables for the benefits they offer: a) chemical inertness in a wide variety of reaction environments, including harsh chemicals such as chlorine gas or hydrofluoric acid; b) thermal resistance to low and high temperatures (above 150°C); c) steam resistance for sterilization; d) good cleanability, to avoid contamination between production batches and growth of bacteria, mold or other contaminants; e) high flexibility (for the movement of diaphragms in pumps, valves and pressure regulators). In addition, PFAS are contained in many reagents, intermediates, solvents, ligands and catalysts used in pharmaceutical production and R&D (e.g. trifluoroacetic acid (TFA), hexafluoride isopropanol and trifluoroethanol in peptide synthesis, TFA in vaccine production, etc.). **Quality Control**: There are many PFAS used in the quality control of most medicines, including TFA, a critical reagent used as a co-solvent or buffer in many

analytical methods described in the official pharmacopoeias that drug manufacturers are obliged to follow.

Packaging:

Various types of fluoropolymers used in primary packaging (i.e. those directly in contact with the drug) protect medicines from air, moisture, impurities and contaminants, safeguarding the quality and safety of the products throughout their shelf life.

Main applications:

- Production of active pharmaceutical ingredients
- Excipients in pharmaceuticals
- Pre-dosed inhaler propellants (MDIs)
- Pharmaceutical production equipment: reactor coating, seals, gaskets, piping, non-stick coating, surfaces, filtration units etc.
- Disposable consumables: filters, bags, tubes, etc.
- Laboratory analytical equipment: tubes, valves, gaskets, filters.
- Raw materials, chemical intermediates, reagents, solvents, catalysts, ligands, auxiliaries in pharmaceutical production.
- Chemical production of active pharmaceutical ingredients (APIs) containing PFAS: PFAS raw and starting materials and intermediates (building blocks of the API molecule).
- PFAS materials and reagents used in quality control activities required by regulations such as European Pharmacopoeia monographs (e.g. trifluoroacetic acid (TFA) in the mobile phase of high-performance liquid chromatography (HPLC), perfluorobutanoic acid (PFBA) as ion pair reagent in chromatography.
- Refrigerants in heating, ventilation and air conditioning (HVAC) and low-temperature refrigeration equipment,
- Refrigerants in laboratory equipment (temperature-controlled centrifuges)
- Packaging of medicinal products: blisters, sachets, tubes or other metal or plastic containers, vial caps or other coated elastomers.

The restrictions do not provide for a general exemption for medicinal products, therefore, the production of active pharmaceutical ingredients (APIs) using, for example, polyfluorinated starting materials and the placing on the market of these APIs and the in vitro medicines and diagnostic devices containing them, are potentially subject to the restriction on PFAS. PFAS materials used in manufacturing processes, medical devices such as non-woven surgical drapes and gowns to make them waterproof and oilproof and stain-resistant, in medical implants/prostheses or packaging (see below for more information), also fall within the scope. The use of fluoropolymers is very widespread in the packaging sector for the packaging of medical instruments or drugs in aseptic conditions and, as for API, their replacement

	is currently difficult.
Medical Sector	• Implantable medical devices, including interventional cardiac occluders and endoprostheses, surgical vascular grafts, cardiovascular patches, heart patches or tissue implantable heart valves, surgical sutures, implantable ophthalmic applications, hernial mesh, endoscopes. • Devices used in vascular surgery, including guide wires to access target vessels, pass through lesions and administer therapy to the target region of the vessel itself, vessel closure devices (an integral part of large-caliber arterial procedures). • Electrosurgical devices for ultrasound dissection or, more generally, for treatments involving energy exchange. • Assembly of the main cables of the robotic arms of an angiographic system (FEP, ETFE, PFA). Combination of more than 20 individual cables, which are not in contact with the patient or user as they constitute a fixed installation inside the instrument with different functions: high voltage cables, power cables, control cables, signal cables, etc. • Nuclear magnetic resonance systems, where PTFE is used in cables and sheaths as an insulating agent at low temperatures. Fluoropolymers also play an essential role in enabling imaging (via electronic chips and X-ray semiconductors, magnetic resonance imaging, CT and ultrasound) as well as medical analysis in in vitro diagnostic instruments (blood, tissue, urine tests). • PFAS (PTFE) are used in the assembly of the main cable of various lengths and number of conductors in blood gas systems. • Intensive care devices and systems, including intensive care ventilators, anesthesia machines, incubators, patient monitoring systems, medical equipment supply systems, hospital gas management systems. • Complex equipment, including active medical devices used to replace essential bodily functions in acute or chronic organ failure, keeping the patient alive. It is estimated that more than a hundred different components, consisting of different fluoropolymers (e.g., biocompatible valves, O-rings, batteries and electronic components) are involved in complex equipment of this kind. • Analytical equipment for in vitro diagnostics, within which PFAS such as PTFE, Kynar, FFKM, PVDF, FEP, Viton, etc., have essential applications within the fluidic path of analyzers (e.g., tubes and O-rings). • Production and packaging of disposable components or devices, also used in a sterile state. • In vitro diagnostic devices such as test kits for hemostasis (at extremely low concentration and volume) that detect blood clotting. • Heat transfer agents in instruments for clinical chemistry IVD diagnostic tests, as well as additive in chromatographic analysis (e.g., TFA in mobile phases).

	• Packaging of cartridges for immuno-dosage. • Glucometers, for the measurement of blood glucose also for lay use (e.g., electrical appliances, PCB printed circuits, cable insulation. • Systems for disinfection of contact lenses. • Devices that constitute an integral drug-device combination, such as pre-filled syringes containing PFAS-coated cap drugs (ETFEs) to provide a barrier effect against rubber-extractables. • Fluorinated waxes are used, alone or in combination with other waxes, as an anti-rubbing and slipping additive in printing inks which are in turn used to create markings for identification, scale, measurement, size and other functional attributes on medical devices and on the device part of an integral drug-device combination. • Filters for sterile containers, needle recovery systems, tracheosto, laparoscopic catheter guide wire, valves, fittings, pumps, tubes and linings of medicine inhaler containers. • Ubiquitous use in different medical and in vitro diagnostic devices such as components such as hoses, gaskets and other parts that carry gases, electrochemical sensors, lubricants, valve coatings, membranes for filtering and venting. • Special lubrication for O2 cylinders, catheters and diaphragm knobs • Conformational coatings for: stents, pacemakers, laparotomy systems, microsurgery, implantable systems for the control of physiological parameters, drug delivery systems.
Chemicals & Energy	• Air filtration for gas turbines using fluoropolymers is highly efficient in capturing virtually all particles even in harsh wet and wet conditions for a long service life compared to other filtration systems. • Mercury control systems for coal-fired consumers use fluoropolymers in the fixed adsorbent system to capture elemental and oxidized gas-phase mercury from industrial exhaust gases containing SO3. • Tanks, vessels, pipes, pipes, column packaging, heat exchangers, pumps, filters, gaskets and/or coating of these components • Power and data cable isolation • Heat exchangers for coal and waste incinerators and desulphurisation units • Battery collectors • Chlor-alkali processes • Gas handling, filtration and sampling of fluids in the nuclear industry
Waste sector and recycling/reuse	Particular attention should also be paid to the waste sector and to the recycling/reuse of materials, a key sector of the ecological transition and the circular economy, which are affected at the end of life by products and choices made in the supply chain. Even when some substances are banned,

<table>
<tr><td>of materials</td><td>or severely restricted in production processes, they will still be present in waste, even after many years, depending on the length of the life cycle of the products. The presence of persistent organic pollutants (POPs), including recently introduced PFOA and PFOS, in waste analytical profiles may require very expensive decontamination and treatment processes, or require extensive monitoring plans for certain substances. In order to apply the best waste management treatment, information shared throughout the chain on hazardous substances is essential. Therefore, the exchange of information and any information from the manufacturer on how the product can (and should) be treated safely at the end of its life cycle can be very important for the waste management chain and its subsequent reuse, as an EoW (End of Waste) material.</td></tr>
<tr><td>Gas infrastructure</td><td>combustible gas pressure regulators;
safety devices for combustible gas pressure;
complementary equipment for pressure control stations;
safety and control devices for burners and gas appliances;
complete stations for pressure control and measurement of combustible gases;
Fuel gas odorization equipment.</td></tr>
<tr><td>Metalworking</td><td>Welding and Cutting Equipment oxy gas, arc and resistance
Valves including cylinder valves
Pressure regulators
Flow regulators
Gas distribution systems
Welding and cutting torches and heating
Low pressure safety devices
Pipes (low pressure and high pressure)
Torches
Welding machines and manual, automatic and robotic cutting systems, fume extraction systems
Fluoropolymers are typically used as sealing solutions (e.g. gaskets; Or ring;) and are used for their properties to obtain:
resistance to high temperatures
resistance to aggressive chemicals
low friction
Impact resistance
Long-term stability</td></tr>
<tr><td>Industrial automation,</td><td>Industrial automation, monitoring and control (IAMC) equipment includes devices used to automate industrial processes, control systems and</td></tr>
</table>

monitoring and control	associated instrumentation. The scope of the equipment consists of complex electromechanical products that measure parameters such as temperature, humidity, pressure, corrosion and density, as well as process control products such as valves, actuators, flow measuring devices and regulators. A number of different fluoropolymers, including fluoroelastomers (such as PTFE, PCTFE, EFTE, PFA, FEP, FKM and FFKM), are used in critical components of IAMC equipment such as coatings, gaskets, valve seats, wires and cables, and electronic components.
Other uses	Industrial applications for compressed, liquefied and dissolved gas • Equipment for the production, filling of cylinders and other containers, transport (also regulated ADR / TPED), handling, distribution in buildings, pressure reduction and dosing of gases for industrial, professional, consumer, medical, respiratory, aerospace, food and all other applications of compressed, liquefied and dissolved gases Used as emulsifiers and surfactants in cleaning products and in the formulation of insecticides. For example,: • Surfactants used as processing aids in emulsion synthesis of fluoropolymers • cleaners (for glass, metal, ceramic, carpet and upholstery) • dry cleaning products; waxes and polishes (e.g. furniture, floors and cars) • windshield wiper fluids, windshield treatments (for cars), water-repellent fluids • Skin care products, toiletries, hair products, perfumes and fragrances Used in refrigerant gases for the air conditioning of vehicles (e.g. agricultural) and in sealing materials (for example in gaskets, sealants) used in industrial environments. **With regard to the capital goods/machine tools/agricultural mechanization sector**, the total ban on PFAS would impact numerous elements used in the construction of these machines, for example: • electrical, electronic, semiconductor devices; • hydraulic and pneumatic systems; • mechanical gaskets and seals; • lubricants, elements resistant to high temperatures and / or chemical agents. It should also be taken into account that, in many situations, there are no alternative materials capable of replacing PFAS. This would lead to a loss of competitiveness and technological excellence in a key sector for the national

	economy and exports.

In addition to all the specific sectors analyzed, it is important to emphasize that any industrial plant uses materials/equipment containing PFAS. For example, they can be used in the following categories: process units, including environmental protection equipment (waste water treatment, gas purification units), safety and security, energy and services, other equipment, including on-site transport, other products (greases, lubricants, catalysts, coolants, equipment-related process/auxiliary adjuvants, sealants, valve and piping coatings, gaskets, membranes, filter materials, foams, mold release agents, conveyor belts, O-rings, columns/interiors, diaphragms) or paper filters. Specifically, it is important to emphasize that all PFAS used in products are essential to maintain safety, in order to avoid fluid leakage with risk of fire and/or explosion.

To the best of our knowledge and, as reported by our member companies and by them to their suppliers, the PFAS used in the cases mentioned above would be - at the moment - difficult to replace.

Without these materials/equipment, industrial plants can no longer function.

In addition, it should be noted that information on "uses" has been collected with extreme difficulty.

In fact, to date, there is no legislative obligation on the part of suppliers to communicate any presence of PFAS in the articles supplied (unless some of these are also substances of very high concern or subject to restriction according to REACH).

In addition, it is difficult to accurately assess the presence or absence of PFAS given the low concentrations indicated (25 ppm /250 ppm) in the restriction proposal.

Therefore, additional time would be needed to obtain more information along the supply chain and to allow the industry to adapt to a possible restriction.

3.1 The Focus on F-gases

F-Gases have physical properties such as to maximize the energy efficiency of refrigeration and air conditioning systems, to guarantee the safety of operators and end users and to reduce, through the use of HFO (hydrofluoroolefin, very low greenhouse effect IV generation refrigerant gas), the environmental impact in terms of CO_2 equivalent. Their use, as refrigerants and blowing agents of insulating foams, and end-of-life management are already regulated by Regulation (EU) 517/2014. In particular, for use as refrigerants, the Regulation requires periodic checks of gas leaks, encourages recycling and regeneration and ensures that the product is treated by expert personnel, effectively reducing the possibility of uncontrolled emissions into the environment.

These periodic checks will be further detailed in the upcoming revision of the Regulation, due to enter into force at the beginning of 2024.

If F-gases were to be restricted, the impact on the entire value chain of the Refrigeration, Air Conditioning and Heat Pumps (RACHP) sector would be very significant.

Moreover, in the absence of derogations, given the use of these gases also in the semiconductor sector, the latter could find itself unable to continue production, with repercussions on the entire supply chain, not only in Europe.

Substitutes are not feasible in all applications: in some cases due to space constraints, equipment in others due to low energy efficiency or because the risk associated with flammability or toxicity is not acceptable or minimizable. In most cases it is not possible to simply replace the gas, but the redesign and / or replacement of the entire system is necessary.

In fact, "natural" refrigerants are not suitable for replacing HFCs in existing systems and, therefore, if a ban on PFAS (which includes almost all HFCs and their HFO substitutes, with almost zero greenhouse effect) were imposed, over 90% of Refrigeration, Air Conditioning and Heat Pump systems would have to be replaced within a few years, With a very high cost for the community and with a huge load of products to be disposed of.

Therefore, inadequate *phase-out* times do not allow industry to introduce alternative substances into the equipment in time, as the redesign and development of new equipment must be done addressing issues of consumer safety, energy efficiency of the equipment, as well as feasibility or cost.

For this reason, it would also be appropriate to take into account the developments of the revision of Regulation (EU) 517/2014 at the procedural stage of the interinstitutional negotiation (Trialogue), as the application of concomitant prohibitions could put the sector in serious difficulty.

A further aspect to be taken into consideration is the fact that HFCs and HFOs are not classified as persistent or very persistent, as they have a limited atmospheric life, and numerous evidences show that only for a limited number of F-Gases the degradation product in the environment is TFA (trifluoroacetic acid).

3.2 The Focus on fluoropolymers

Fluoropolymers as part of the ecological transition

Driven by global mega-trends such as the energy transition and digitalization, fluoropolymers are increasingly used in innovative products: from transport equipment, electronics, construction, industrial equipment and renewable energy. They therefore play an essential role in most EU strategies, as explained below.

As part of the European **Green Deal**, the European Commission has shared a proposal to revise the Renewable **Energy** Directive, which provides the legal framework for the development of renewable energy in all sectors of the EU economy. The Commission calls for further development of green energy sources and has set a target of at least 42.5% renewable energy in Europe by 2030.

Fluoropolymers play a critical role in the development of alternative energy sources and have already contributed to significant technical advances in solar power generation and production efficiency. They can be used for a variety of renewable energy sources such as hydrogen or photovoltaic (PV). Their properties make them ideal for withstanding all the adverse weather conditions that renewable energy plants such as solar panels have to withstand (they must be able to withstand a variety of extreme conditions, as their location outdoors could expose them to high temperatures, wind and humidity, UV radiation and even chemicals).

By providing greater strength and longer life, fluoropolymers have the potential to generate greater efficiency of solar panel installations in a cost-effective manner. Combined with their applicability in various components of renewable energy installations, fluoropolymers can play a significant role in achieving the ambitious decarbonisation targets of the EU energy sector. Given the fundamental function of fluoropolymers in renewable energy sources such as hydrogen, a potential ban could risk compromising European strategies, such as the EU's Hydrogen Strategy, a fundamental framework to support the decarbonization of the EU in a cost-effective way and which aims to produce 10 million tons of renewable hydrogen by 2030.

Fluoropolymers have also played a crucial role in helping to drive forward the remarkable advances in the semiconductor industry that are critical, for example, for renewable energy production. The operation of photovoltaic cells, which form the basis of solar panels, relies heavily on the physical properties of semiconductor materials. They also act as efficient rectifiers, leveling the electric current exploited by renewable sources, to ensure minimal energy loss.

They therefore have the potential to generate greater efficiency of renewable energy sources.

Through the EU Chips Act, the European Commission is seeking strategic independence to promote both the economy and the green transition. The European Union aims to double the market share of European semiconductors by 2030, which is now set at 10%. The investment will promote innovation, technical and technological skills within the European Union.

In terms of energy storage, the European Commission estimates that the EU will need to be able to store six times more energy than today to reach net-zero greenhouse gas emissions by 2050. The Green Deal aims to boost energy storage capacity in Europe to contribute to the decarbonisation of the energy sector.

Therefore, innovative energy storage solutions will play an important role in ensuring the integration of renewable energy sources into the EU grid at the lowest cost.

In this sense, new battery technology projects are emerging, such as lithium-ion batteries and vanadium redox flow batteries. These technologies should not only provide the grid with the storage capacity needed to incorporate renewable energy but are also key to enabling the flexibility needed for the energy transition. This essential feature is necessary for the materialisation of the future "green" grid, as production from renewable energy sources is subject to more significant fluctuations than the traditional fossil fuel grid.

While working at European level to reduce greenhouse gas emissions, batteries are playing an increasingly important role, not only for the rapid increase in electric mobility, but also for their ability to balance supply and demand within the electrical system. To keep up with current goals, it is necessary to make the most of energy storage technologies, of which fluoropolymers are an essential element.

Limiting the use of fluoropolymers will increase the cost of different types of batteries, hindering the transition to electric mobility and increasing the cost of key technologies needed to increase the share of renewable electricity in our grid, which can affect electricity prices.

In addition, limiting the use of fluoropolymers (without adequate derogation) could also have the unexpected consequence of preventing semiconductor production and, therefore, drastically reducing the benefits mentioned above.

Fluoropolymers also play a crucial role in helping to promote advances in energy efficiency in architecture. Adequate insulation of buildings is essential to improve their energy performance, as it prevents heat loss. In the European Union, almost 75% of buildings are energy inefficient. Collectively, buildings in the EU are responsible for 40% of our energy consumption and 36% of greenhouse gas emissions, which mainly result from construction, use, renovation and demolition.

Through the revision of the Energy Performance of Buildings Directive, the European Commission is seeking to introduce EU-wide minimum energy performance standards for the worst performing buildings. This revision aims to improve the existing regulatory framework to reflect higher ambitions and more pressing needs for climate and social action**. Fluoropolymers are key to the EU achieving this dual objective. They provide durable building materials, even in extreme environmental conditions, thermally stable and easy to clean that can reduce building cooling costs and energy consumption. They guarantee greater fire safety, as they ensure the absence of flame propagation and low smoke generation and allow the weight reduction of building structures**.

One of the objectives of the Green Deal is to reduce greenhouse gas emissions from transport by 90% by 2050. Aviation is a key area of interest in reducing emissions and achieving this goal. **Fluoropolymers play a crucial role in helping to promote fuel efficiency in the aerospace industry: they provide long-lasting and effective protection against heat, aggressive fluids and fuels, thus extending the useful life of various components critical to emission control and safety.** To fly safely, modern aircraft also require the installation of hundreds of kilometers of cables and wires. These wires are often insulated with at least one layer of fluoropolymers, which are crucial for aircraft to withstand low temperatures and improve fire safety. In addition, they also guarantee a reduction in the weight of key components which is essential to achieve lower fuel consumption and emissions into the atmosphere.

In accordance with European policies for waste reduction and product durability, it is good to remember how PFAS, with their characteristics of durability, allow to contribute to sustainability by obviating the early obsolescence of products. As an example, some plastic fluoropolymers, such as PVDF, are used as sealing components (e.g. for diaphragms, gaskets, pipe coating, etc.) in machines used in the agricultural and gardening sectors, thanks to their excellent mechanical resistance, abrasion and corrosion characteristics, thus contributing to the durability of the product.

High molecular weight fluoropolymers such as polytetrafluoroethylene (PTFE), widely found in different product categories even apparently distant from each other but interconnected (e.g. components of medical devices), are non-toxic, extremely stable, too large to be bioavailable and do not have the potential to spread in the environment. As a result, PTFE and many other fluoropolymers meet the 13 criteria set by the OECD for low-risk polymers. Their impact on the environment or human health is considered minor and they can be produced, processed, used and disposed of responsibly, using best practices for industrial control technologies.

4. Lack of analytical methods and possibilities for verification of the restriction

The PFAS restriction proposal recognises that its applicability depends in part on the availability of sufficiently efficient and effective analytical methods for monitoring, which are rapidly developing. **At present, however, for many uses (electronics and electronic equipment incorporating semiconductors, fluorinated gases and refrigerants, in vitro medical and diagnostic devices and medicinal products, cosmetics, petroleum gases and mines, metal plating, flame retardants and resins) there are no standard methods for measuring PFAS: this is an issue that needs to be addressed before the restriction becomes effective,** considering the wide impact of the restriction proposed to date in several areas, including that of human health.

Currently commercially available **analytical tools** and **methods** for detecting PFAS, such as in wastewater, are believed to allow visibility of only a small fraction. This is due to the limitations of current analytical methods and the large number of PFAS species in use.

In this sense, the industry has examined what it considers a short list of analytical techniques capable of detecting certain species of PFAS within wastewater. However, it was not possible to identify an analytical method that could detect all PFAS comprehensively. **Consequently, it is essential that further research is conducted to advance such analytical techniques.**

In this regard, the following are some survey techniques to quantify PFAS:

1. US EPA 537.1 (modified)
2. US EPA Draft 1633 (EPA method in development)
3. US EPA Draft 1621 AOF (EPA method in development)
4. Liquid Chromatography-High-Resolution Mass Spectrometry (LC-HRMS)
5. 19F Nuclear Magnetic Resonance (NMR)
6. BS EN 14852
7. ISO 21675:2019 – Water quality: Determination of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in water. Method using solid phase extraction and liquid chromatography-tandem mass spectrometry (LC-MS/MS) - Detection limit 10 ng/L (drinking water), 20 ng/L (wastewater)
8. ASTM 7979 Standard Test Method for Determination of Per- and Polyfluoroalkyl Substances in Water, Sludge, Influent, Effluent, and Wastewater by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS)
9. EPA OTM-45 Other Test Method 45 Measurement of Selected Per- and Polyfluorinated Alkyl Substances from Stationary Sources

In addition, it is necessary to highlight the lack of analytical methods for verifying the conformity of products containing PFAS, as it could represent a problem both for the industries that produce and use these products, and for the control authorities that will have to carry out compliance checks.

5. Possible direct and indirect impacts on sectors of national interest

The impact of the PFAS restriction in the sectors analysed below can be direct or indirect. It will be direct where the restriction causes the impossibility of constructing/assembling the complete object and involves the need to identify a new production process, while it will be indirect when the restriction makes it impossible to supply the components necessary for the construction/assembly of the object.

This overview makes it clear that the application of such a wide restriction without having thoroughly assessed the risks and benefits of its application, will entail, among others, the inevitable consequence of penalizing the national or more generally European industry, leader and example worldwide in many sectors for safety and innovation, to the advantage of non-European markets that do not apply such extensive restrictions on PFAS.

Use/Production	**Associations concerned**	**Presence of alternatives**	**Bestowal**
PFAS production	Federchimica		
Coatings (valves, pipes, pumps, balls, compressors)	Aquitalia, UCIMAC, Assopompe, ASSOCLIMA, ANASTA, AVR, APPLiA Italia, ANIE, Assogomma, Confindustria Dispositivi Medici, COMPO, Assogastecnici, Anfia, UCRS, ACISM, UCC	NO	WEEE
Seals	Aquitalia, UCIMAC, tecnologie vending, Assopompe, AVR, Assogomma, ASSOCLIMA, ANASTA, FEDERUNACOMA, APPLiA Italia, ANIE, Confindustria Dispositivi Medici, AIAD, COMPO, Assogastecnici, Anfia, UCRS, ACISM, UCC	NO	WEEE, landfill
Sealants	UCIMAC,	NO	Dump

	FEDERUNACOMA, AIAD, COMPO, Anfia, UCC		
Greases/lubricants	UCIMAC, AVR, ANASTA, APPLiA Italia, ASSOCLIMA, ANIE, Confindustria Dispositivi Medici, AIAD, COMPO, Assogastecnici, Anfia, UCRS, UCC	NO	WEEE
O-rings	UCIMAC, vending technologies, Assopompe, AVR, ANASTA, APPLiA Italia, ASSOCLIMA, ANIE, Confindustria Dispositivi Medici, AIAD, COMPO. Assogastecnici, FEDERUNACOMA, Anfia, UCRS, ACISM, UCC	NO	WEEE
Pipes	UCIMAC, vending technologies, Assogomma, APPLiA Italia, AIAD, Anfia, UCRS	NO	WEEE
Semiconductors, Components & Electronics	ANIE, UCIMAC, ASSOCLIMA, APPLiA Italia, Confindustria Dispositivi Medici, AIAD, Anfia, ACISM	NO	WEEE
Refrigerants	ASSOCOLD, ASSOCLIMA, FEDERUNACOMA, APPLiA Italia, Confindustria, Anfia Dispositivi Medici, AIAD, Assogastecnici, Anfia	Yes, but only for some uses for safety problems (flammability and high operating pressures) and energy efficiency.	WEEE, Consortia for the collection of refrigerant gases (product regeneration)
Foams	ASSOCOLD, ASSOCLIMA, APPLiA Italia, Confindustria Dispositivi	Yes (high investments and time)	WEEE (extracts and treated)

	Medici		
Valves	AVR, Assogomma, Confindustria Dispositivi Medici, AIAD, Assogastecnici, Anfia	NO	Separate waste collection or landfill
Taps and fittings	AVR, UCRS	NO	Separate waste collection or landfill
Non-stick coatings (Consumer use with spray and roller coating)	FIAC, APPLiA Italy	Sometimes there are alternatives but with lower performance and higher costs. In some cases there are no	Separate waste collection
Paper filter media	Assocarta	They are studying alternatives	Incinerator
Technical fabrics for sun protection and outdoor furniture	SMI	NO	Separate waste collection
Technical protective clothing for motorcycle use	ANCMA	NO	Dump
Stain-resistant, water-repellent and anti-stitching treatments		They are carrying out studies but there is less performance	Dump
Hydraulic systems for agricultural machinery	FEDERUNACOMA, Assogomma		Dump
Welding	ANASTA	NO	Where required according to the type of product; some products are covered by WEEE
Industrial applications of compressed, liquefied and dissolved gas	ANASTA	NO	
Cables	ANIE, APPLiA Italia, Confindustria Dispositivi	NO	

	Medici, AIAD, Anfia		
Insulating gases	ANIE, Confindustria Dispositivi Medici, Assogastecnici, ACISM	We are moving towards both fluorinated and non-fluorinated lower GWP gases, but time is needed for *phase-out*, according to the revision of Reg. 517/2014 still in progress	Recovery as a result of Presidential Decree 146/2018
Lithium batteries	ANIE, Assogomma, Confindustria Dispositivi Medici, AIAD, Anfia	NO (they are carrying out studies but there are lower performances)	Recovery pursuant to d.lgs. 188/08
In vitro medical and diagnostic devices	Confindustria Medical Devices	NO (in some applications alternative solutions are being studied, but with lower performance)	Miscellaneous (WEEE, incinerator, landfill)

In addition, the proposed restriction, if maintained as it stands, could also cause direct negative impacts on the health of European citizens. In fact, the impossibility of using certain PFAS in medical devices and/or in vitro diagnostic medical devices (present in different ways in the non-exhaustive list presented above) could determine the lack of these products on the European market, or the presence of alternatives with lower performance or with a risk/benefit assessment not adequately evaluated compared to what is currently known on the use of PFAS. The consequence, therefore, could be the unavailability of in vitro medical and diagnostic devices within the therapeutic pathways currently envisaged. A fortiori, where the protection and safety of European patients are considered, a risk-based and risk-benefit approach to such a broad restriction should be considered, also taking into account possible cross-sectoral consequences. For example, a large part of the components of medical devices that contain PFAS in different ways is supplied through other industrial sectors, therefore, a more careful assessment of the consequences of such a widespread and intertwined restriction proposal is necessary. In light of these considerations, the application of ECHA's proposed restrictions for PFAS, under the REACH Regulation, especially in the field of medical devices and in vitro diagnostics, should be seen in a broader context that takes into account the potential and wider impact on healthcare in the context of public health protection. The same approach is already (in part) being considered for the field of medicinal products for human use, and the discrimination between the medical and pharmaceutical sectors does not appear to be consistent.

6. Conclusions and proposals

Following the considerations made so far, Confindustria believes that the impact of such a large group restriction will have important consequences on the Italian economic system as if it were approved as currently proposed, in addition to having a direct economic impact on all supply chains that use PFAS, it would block the implementation of most European policies for the future.

In most applications, as we have seen, to date there are still no alternatives to PFAS and, where they exist, they cover only some of the properties of PFAS. That is why we need time to replace these substances and find equally good alternatives in terms of performance.

In this regard, as part of the restriction proposal, we present below some proposals – exemptions and derogations – for some specific sectors, which we reserve the right to integrate further even beyond the terms of the consultation launched by ECHA, producing additional documentation on the subject. While recognising the importance of the safety factor in the use of certain substances, we believe it is essential to carefully assess the potential impact of such a restriction on certain specific sectors, which may require a differentiated approach to preserve the functionality and safety of products without compromising human and environmental health.

In light of the above, therefore, we believe **that an exemption is necessary with regard to fluoropolymers** (plastics and elastomerics). Fluoropolymers, used for example in lithium-ion batteries, fuel cells and electrical engineering and electronics, should be excluded from the restriction, given their non-hazardousness. **In addition, we consider it of paramount importance to establish a dedicated exemption for the semiconductor sector, currently only assumed but not foreseen, covering the entire value chain of the sector.**

The general transitional period of only 18 months for uses not covered by one of the few restricted exemptions provided for, in any case, excludes the possibility of replacement/new products being developed, approved and introduced. However, the same applies to the exceptions provided for in the restriction proposal and to the transitional periods proposed for them which are not aligned with the time needs.

In fact, it should be noted that the **transitional periods** currently proposed are, from an initial assessment, **inappropriate for certain sectors** such as, for example, those of medical devices and in vitro diagnostics and all the others related to them (see, for example, the procurement of components that has applications in different types of products).

The two transitional periods (6.5 and 13.5 years) appear to have been chosen arbitrarily and have no empirical basis in relation to conventional periods of development and certification of certain products.

Consequently**, the final restriction should have objective differences between individual (or groups) of PFAS and set a limit for those substances that have actually been shown to present an "unacceptable risk" (Art. 68.1, REACH). In order for there to be a possibility of fully implementing a definitive restriction in certain sectors, it would be necessary to extend the transition period, carrying out a new assessment taking into account the specificities highlighted by certain sectors and the presence (or not) of equally viable alternatives, as**

well as the timing necessary for the development and placing on the market of alternative products.

In addition to the transitional periods, further changes to the current proposal should be envisaged:

- As regards the **textile sector**, it should be noted that no specific derogations are proposed in the restriction proposal for reclaimed materials. Therefore, in order to allow a correct management of these materials, with consequent positive impacts in socio-economic terms and circularity and sustainability, **we consider it appropriate to point out the need for a specific derogation for the application of the restriction in question (RO2), which refers to articles (textiles) consisting wholly or in part of regenerated raw materials (textiles). In this sense, the duration of that derogation should not be less than 12 years.**

- With specific reference to the **automotive *sector***, it is important to underline that, although the amount of PFAS present in a vehicle is minimal (less than 0.1% by weight), the components and applications involved are numerous and such as to allow the vehicle to start (such as, for example, the starter) and, once started, to brake (for example, brake hoses and pedals), as well as to ensure the durability and strength functions for which most PFAS were made. In addition, there are currently no 1-to-1 alternatives available on the market for many applications.
  For this reason, we consider it necessary for the legislator to take account of these critical issues, as has already happened, for example, with the directive on end-of-screw vehicles (ELV 2000/53) when, for heavy metals such as lead, **temporary exemptions were granted** for certain **non-substitutable applications**.
  In addition, we believe that **an exemption is also needed for spare parts**, in accordance with the principle of 'repair as produced', which is widely accepted in the European Union and already applied in current legislation.
  In our opinion, therefore, **the proposed transitional period for the restriction, especially for refrigerants for the air conditioning system, in the automotive sector should distinguish between new types of vehicles (new type-approved) and new registrations (of existing models) and between passenger cars and heavy vehicles**.
  The aforementioned air conditioning system also deserves specific mention. The planned restriction must be applied only to new approvals, providing for a longer time horizon (13.5 years). In fact, the replacement of the coolant in the climate system implies the redesign of the entire climate system and the engine compartment; action unthinkable on models already in circulation. In addition, such an extension of the derogation may ensure a reduction in the risks due to the possible use of highly flammable gases.

- For **the Agricultural and Forestry machinery** sector (and related spare parts), the application of the same derogations applied to the Automotive sector is required, given the similarity of the supply chain and the strategic role they play for European food needs. **Indefinite exemption for plastic and elastomeric fluoropolymers in light of their particular performance characteristics considering that to date, there are no valid alternatives on the market.**

- In the industrial**, medicinal and food gases** sector, the use of PFAS (e.g. in gaskets, valve seals, etc.) makes it possible to exploit its almost universal compatibility characteristics with all types of gases, as well as the resistance to the extreme temperature conditions of cryogenic gases (e.g. -269°C in the case of helium). In the case of lubricants for industrial machines, they also guarantee the necessary resistance to combustion in strongly oxidizing environments (e.g. pumps for oxygen use).

To date, there are no known alternatives to PFAS that present the same degree of safety in the use of compressed gases and as regards cryogenic applications, there are some reference standards (e.g. ISO 11114 and ISO 21010 series) that identify only PFAS as compatible materials. It should be noted that these standards are based on many years of experience and tests carried out on materials by laboratories such as the German Bundesanstalt für Materialforschung und -prüfung (BAM), a Federal Technical Scientific Institute that carries out tests and research with the aim of "protecting people, the environment and material goods – source website to be evaluated on use or not".

The execution of tests for the identification and approval of alternative materials to PFAS, with the same characteristics of compatibility and safety in the use of the various gases produced and / or marketed by the sector, involves times that are not compatible with the deadlines set by the current restriction proposal.

With regard to the F-gases sector, it is also important to underline that their management is already adequately regulated by EU Regulation 517/2014 (also known as the FGAS Regulation) which imposes specific obligations on operators. The Regulation has, in fact, not only reduced the amount of HFCs placed on the market but has also generated a decrease in emissions into the environment. The reduction has been estimated to be 70% compared to 1990 values and this positive trend is expected to continue to grow in the coming years.

Although there are already exceptions for some applications**, we believe that a total exemption is appropriate, especially for gases used for the maintenance and recharging of refrigeration and air conditioning equipment already in use**. In fact, it is not possible to replace the refrigerant gases currently used with non-PFAS alternatives without having to make substantial changes to the systems, thus implying high costs for the community.

- With specific reference to the **household** appliance sector, it is correct to underline that PFAS are used in a wide range of products (about 65%) with low quantities per single appliance, but the components and applications that use fluoropolymers are extremely specific and critical for the operation, performance and durability of the product itself. Moreover, currently, for many of the applications there are still no 1-to-1 alternatives available on the market that allow to maintain the same combination of functionality and performance, or the durability of the product and its characteristics during use, or to switch to an alternative component without a complete re-design of both the product and the production process, and management of all the tests connected to this. These critical issues, in addition to new products, also impact on the repairability of the installed appliances due to the lack of spare parts suitable for the design of the product already on the market. Therefore, the proposed generic restriction for all fluoropolymers would have a negative socio-economic impact, disproportionate in relation to the number of products concerned and the limited period of time.

  We therefore ask that the legislator take into account these critical issues, as illustrated above, or at least carry out a reassessment of the proposed transitional

period for the restriction, linked to accurate technical and scientific assessments, especially in relation to certain uses (for example for materials in contact with food for domestic products, electronic electrics and lubricants), in light of the critical substitution towards alternative materials but that maintain the same combination of functionality, performance and chemical and food safety.
Industry needs to be given sufficient time to transition, intervene in production processes and end products in the value chain, depending on the applications, use, function and status of alternatives, to adapt to new requirements. In fact, a downstream-user can modify the product with times strongly interdependent on the complexity of the supply chain and the presence on the market of a valid alternative in all the validation profiles provided for the finished product.
If the restriction were to come into force across the board, there would be a real risk of seeing entire categories of household appliances disappear from the EU market, or drastically reduce their lives with a consequent increase in waste and costs for the consumer. **For the sector, therefore, a derogation for fluoropolymers of 12 years, with a possible revision within 6 years of publication, would be desirable.**

- It is also important to highlight the impact that the proposed restriction could have on the **pharmaceutical sector.** The restrictions envisaged in ECHA's proposal **will have a major impact on research, development and production of medicines in the EU.** In this regard, it is highlighted that, although active pharmaceutical substances containing PFAS are excluded from the restriction proposal, **the proposal prohibits the use of precursors and raw materials necessary to produce these active substances**. There are currently 300 medicines marketed containing PFAS in various therapeutic areas (oncology, cardiovascular, viral diseases, etc.), and 500 those in development); Today, about 30% of all pharmaceutical active substances contain fluoride. Given the peculiar chemical properties of fluorine, the use of alternative chemical groups not containing PFAS would have serious repercussions on the tolerability and efficacy profile of the drug. Therefore, a restriction on the production of medicines containing perfluoroalkyl groups **would no longer allow the marketing of such medicines in the EU, with serious consequences for patients, in particular those suffering from diseases where treatment options are limited.** In addition, the restriction covers all other PFAS substances widely used in the life cycle of all drugs (including those not containing PFAS), in reagents, equipment and consumables used in R&D, production, quality control, as well as in certain primary packaging, excipients and propellants. As a result, European R&D and manufacturing sites of pharmaceutical companies will not only develop or produce the many PFAS-containing medicines but will face severe limitations on the development and production of all other medicines, and EU health systems will be at risk of shortages. This could also have a serious impact **on the quality of health services and Europe's competitiveness in the pharmaceutical sector.**
  Medicines in Europe are subject to strict and specific industry regulations to ensure their quality, beneficial effects on health and safety of use; they are also subject to the Environmental Risk Assessment (ERA), for which the proposal to revise the pharmaceutical legislation in progress already provides for even more stringent requirements, which would be added to what is already provided for by the other regulations currently under discussion (e.g. packaging regulation; urban waste water directive; industrial emissions directive). In

addition, ECHA's proposal introduces additional requirements that conflict with existing specific legislation regulating the pharmaceutical sector.
In conclusion, therefore**, in our opinion, ECHA's restriction proposal should not apply to the entire pharmaceutical sector and its entire supply chain, not only to PFAS-based medicines and active pharmaceutical ingredients, but also to all those PFAS-containing raw materials, intermediates, reagents, equipment and consumables, without which the research, the development, nd the production of production of medicines in general would not be possible,** with serious harm to patients.

- As regards medical devices **and in** vitro diagnostic medical devices, the proposed restriction poses major risks of future product availability. In fact, the new Regulations (EU) 2017/745 and 2017/746 governing the legal requirements for the medical sector, impose strict requirements for the selection of materials, biocompatibility, modification and validation of the product design, as well as its safety and quality. The ultimate goal is to ensure that only effective and safe devices are placed on the European market. In this scenario, one of the main challenges facing the industry is that the physicochemical properties of PFAS are at the same time the very reason why they are widely used in medical technology and concern for the environment (mainly persistence). Therefore, often the only viable alternative to the use of a given PFAS (if it is available) is another type of PFAS, which does not comply with the purpose of the proposed ban. Otherwise, if a viable alternative material were available, it would be necessary to assess its suitability for use, which must be at least at the same level of performance as the PFAS it intends to replace, as well as its short- and long-term safety and performance. All these steps can take several years, starting from the identification of a new material, through the design of the product, to the evaluation of performance during the relevant time period, up to the clinical aspects in order to meet the intended medical purpose of the device. However, this is not the end of the process because the change will have to be registered and approved by the Notified Body, the third-party body responsible for issuing and maintaining the CE certificate. Finally, it should be noted that the burden of work on the part of these bodies was one of the reasons that led the European legislator to amend the transition times, lengthening them, for the full application of Regulations (EU) 745 and 746. **The risk of applying a restriction to PFAS that is not properly assessed would be the impossibility of producing in vitro medical and diagnostic devices, life-saving products essential for the care and treatment of European patients. Therefore, medical devices and in vitro diagnostics should find greater exemptions in the proposed exemption of PFAS, due to their socio-economic impact at European level.**
- The **Aerospace and Defense** sector is severely impacted by the proposed restriction, with important economic consequences. PFAS chemicals are widely used in the **production**, operation **and maintenance** of A&D products and /or in the manufacture of components (articles), subassemblies and formulations (mixtures) in the supply chains of the A&D sector which includes, but is not limited to, the following products:
    - Commercial aircraft for the transport of passengers and cargo - both fixed-wing aircraft and helicopters;
    - Military aircraft, including fast jets, training aircraft, large transports and helicopters;
    - Military ships: surface ships, including aircraft carriers, and submarines;

- Land vehicles: tanks, communication vehicles, launchers and transport vehicles for military personnel and ammunition;
- Weapons: ammunition systems and weapons;
- Firefighting systems: Agents used in total flooding (Cargo compartment & auxiliary power unit (APU), engine bays) and jet (portable cabin and avionics systems) including Halon, HFC and 2-BTP;
- Equipment designed to be sent into space.

What characterizes the A&D sector are peculiarities that have not been taken into account in the drafting of Annex XV, such as:

- Extremely high product complexity; which integrates a wide range of technologies, advanced materials, electronics and software to provide cutting-edge, high-value products and systems;
- Long service life; with equipment that should have a useful life, in difficult environmental conditions, measurable in decades;
- Safety and reliability requirements: equipment in the A&D sector is designed, used and maintained to minimize the probability and consequences of failure, while operating at the limits of the technologies and materials involved;
- Extended supply chains: the range of subsystem and stakeholder technologies requires large transnational supply chains with many highly specialized sub-levels;
- Strictly controlled technology development, qualification, certification and industrialization processes, to manage development risk and ensure that final products are safe and reliable;
- Product maintenance and logistical support, including spare parts, after the cessation of production, in accordance with the requirements of the original design.

In order to better understand the impact on the sector, a mapping of the types of PFAS and uses where it is evident that they are ubiquitous in the production, operation and MRO (maintenance, repair and overhaul) of A&D products; **Fluoropolymers are the most common type of PFAS (about 80% of A&D uses)** found in articles (gaskets, cables, etc.), or integrated into articles (paints, coatings, sealants, etc.) or components of mixtures (e.g. lubricants, detergents). The impact of the restriction as currently drafted would be felt significantly as early as 18 months after entry into force, as **several applications have been assessed and/or not covered by derogations**. Those applicable seem limited, for the A&D application areas ((5-i, 5-k, 5-m, 5-o, 5-q, 5-s, 5-x, 5-y, 5-dd, 6-o) and **the exemption periods granted, 5 or 12 years, inadequate for a sector affected by stringent qualification and certification requirements, particularly long service life and certification requirements of spare parts, even for products no longer in production**.

Replacing with alternatives is a very long process that takes decades and impacts tens of thousands of parts, components and subassemblies as well as a redesign of components and assemblies necessary if the replacement does not guarantee the same performance as the initial design. To date, we can say that there are generally no suitable alternatives available, with few exceptions and where replacement has been underway for decades (e.g. the replacement of halon gas in fire protection systems).

Note that prior to this proposed restriction, there was no regulatory guidance regarding the use of fluoropolymers, and no drivers to develop/substitute parts and components other than technological progress.

Due to the ubiquity of PFAS in production, operation and MRO, thousands of components, parts, systems, etc. would have to exceed qualification and certification requirements again. The scale of substitution activities that would have to be undertaken would be unprecedented and would derail all ongoing R&T and R&D activities, such as the transition from internal combustion engines, fuel-driven, to hydrogen-powered fuel cells where fluoropolymers contribute decisively to the decarbonisation roadmap of the A&D sector (see contribution from Hydrogen Europe, "Destination 2050 - A ROUTE TO NET ZERO EUROPEAN AVIATION").

An analysis of the economic impact of the non-use scenario describes an exceptionally serious picture; when the restriction comes into force and the waivers expire, all A&D production will have to cease in the EU. All MROs in the EU will have to stop when using affected substances, mixtures or articles, as well as imports of products, parts, components, subsystems and systems for A&D. This is a fatal and disastrous scenario as it would have an impact on the very functioning of the EU in terms of sovereignty in multiple contexts (air transport, defence, security and access to space).

For the A&D sector, therefore, it is essential that the restriction proposal is reviewed, explicitly taking into account the specificities represented so far, proposing adequate and proportionate regulatory risk management measures, such as:

- **Exclude fluoropolymers and fluoroelastomers from the scope of the restriction (**i.e., treat them separately from other types of PFAS);
- **Include a sectoral waiver for non-polymer PFAS uses in A&D,** with a review clause at the end of the waiver period to allow for an extension depending on the availability of suitable alternatives;
- **Recognise the dependence on upstream supply chains for** chemical precursors, substances, mixtures and articles used by multiple industrial sectors for other cross-sectoral derogations, e.g. for lubricants, fire-fighting, transport vehicles, electronics, batteries and semiconductors;
- Include review clauses for all proposed/potential waivers to allow for **an extension depending on the availability of alternatives adapted to the specificities of the A&D sector;**
- **Exclude from the scope of the restriction PFAS required for certified/approved spare parts and legacy spare parts (MROs);**
- Propose measures, for example under the Industrial Emissions Directive, to prevent the release of PFAS into industrial sites to address the risk from emissions;
- Propose measures, for example under the Waste Framework Directive, to prevent the release of PFAS at end-of-life stages to address the risk from emissions;
- Limit the scope of the restriction to professional and consumer uses.

- The restriction proposal would also have a strongly negative impact on the **rubber** sector, which would no longer have materials – fluoroelastomers and other fluoropolymers – with unparalleled properties (first of all thermal and chemical resistance), essential to produce countless components with key functions in various downstream technologies, several of which are the basis of the green and digital transition. The scope of the proposal indiscriminately covers all PFAS, a class defined on the basis of a structural similarity criterion, comprising countless substances, with very different chemical-physical and toxicological properties. It is a simplistic and not scientifically based approach, which also indiscriminately affects fluoroelastomers and other fluoropolymers: non-hazardous materials, particularly stable and chemically inert, considered the choice of choice even in critical applications such as those in contact with food (pipes or gaskets for industrial plants) or in the pharmaceutical sector, precisely because of their chemical inertness and purity (very low levels of contamination).

Given their high cost compared to traditional elastomers, their use is limited to applications where their properties are essential to ensure the required performance, in terms of safety, durability and emission reduction.

Of course, a correct evaluation cannot be separated from the analysis of the entire life cycle of the material, and in this sense the critical aspects related to the production phase, substantially related to the use of fluorinated surfactants, have long been the subject of improvement interventions by the main manufacturers. Further research projects, still ongoing, are aimed at developing alternative production technologies, which do not require the use of fluorinated surfactants, with promising results.

For all these reasons **it is considered that fluoroelastomers and, in general, fluoropolymers should be excluded from the scope of the restriction,** similar to what is already provided for by the Health and Safety Executive (HSE) in the United Kingdom. Any residual risks associated with the production phase may be subject to specific measures.

- **With regard to the chemical industry, an exemption is requested for the use of PFAS in industrial chemical plants**. In particular, PFAS are used in several thousand equipment in chemical plants, mainly fluoropolymers and fluorinated gases.

  The use of PFAS depends on their unique performance properties that are necessary to meet the stringent legal and safety requirements of the chemical industry. For these applications there are currently no suitable alternatives that have the same characteristics as PFAS in relation to chemical, mechanical, thermal and other chemical and physical properties that guarantee safety during operation. Even if such alternatives were found, replacement could take more than a decade with plant interruptions (which would have an impact downstream in all supply chains) and extremely high replacement costs.

- Finally, the addition of the Industrial Automation, Monitoring and Control (IAMC) **sector as a new area of use is deemed necessary** to fill a gap in the list of missing uses in the restriction proposal. The **duration of the derogation for the use of fluoropolymers in that sector should be 12 years**.

  IAMC equipment is critical for the safe, efficient and sustainable production of any semi- or fully automated production process, including those used for the production of most products encompassing the 14 areas of use identified in the proposed restriction of Annex XV of REACH.

  The exclusion of IAMC equipment as a sector of use from the derogations linked to the proposed restriction would have economic repercussions within the European Union, including a negative impact on employment and shortages at European and global level of critical products such as semiconductors, sterilization equipment and raw materials used in the production of chemicals.