

Answer to Echa consultation on PFAS restriction: Annex Question 6 Missing uses – Analysis of alternatives and socio-economic analysis:

The use of PFAS as described in the restriction proposal represents a core component for the valve and taps industry. Fluoropolymers are fluoride-containing polymer-based materials known for their chemical and heat resistance properties.

In particular, fluoropolymers, such as polytetrafluoroethylene, in the valve industry are important for several reasons:

Chemical resistance: Fluoropolymers such as PTFE are known for their outstanding chemical resistance. They can withstand a wide range of aggressive chemicals, including acids, bases and organic solvents. This resistance makes them suitable for use in industrial applications where valves must handle corrosive fluids.

Temperature resistance: Fluoropolymers such as PTFE have significant thermal resistance. They can operate in a wide range of temperatures, from cryogenics to temperatures above 200 °C, without suffering deformation or significant degradation of their properties. This makes them suitable for use in systems requiring the handling of high-temperature fluids.

Low friction and wear: Fluoropolymers such as PTFE have a very low coefficient of friction, which means that they can provide smooth and smooth valve opening and closing action. They also have a low tendency to wear, which results in longer valve life and reliability.

Insulating properties: Fluoropolymers are excellent electrical and thermal insulators. Therefore, valves using fluoropolymers as insulators can provide adequate protection against thermal conduction and the passage of unwanted electric current.

Chemical inertness: PTFE is chemically inert, which means that it does not react with most fluids or materials with which it comes into contact. This property contributes to material compatibility and prevents contamination of fluids. It is particularly advantageous in the food, pharmaceutical and chemical industries, where contamination of products must be avoided.

Fluoropolymers have historically been produced with the aid of perfluorocarboxylic acids, such as PFOA and perfluorononanoic acid (PFNA). Leading international makers of fluoropolymers no longer employ them in favor of substitutes such fluorinated polyether carboxylates (USEPA 2017a).

Furthermore, fluoropolymers, such as PTFE, ETFE, FEP, PFA, PVDF and VDF-co-HFP, are different to other PFAS for the reasons listed below:

- They do not exhibit the toxicological and environmental profiles associated with non-polymeric PFASs that could be considered of concern.
- They have unique physical-chemical properties, which let them very different from non-polymer PFAS and therefore should have a distinct class within them.
- They meet the OECD criteria of Polymer of Low Concern (PLC) and are non-toxic, biocompatible, insoluble and immobile molecules, which are deemed to have insignificant environmental and human health impact.

This information is available in the research literature that shows that fluoropolymers, including PTFE, satisfy the widely accepted assessment criteria to be considered PLCs and therefore are considered to be of low hazard to human health and the environment

For these reasons, fluoropolymers are also allowed for use in medical technology or as materials for food contact, for instance. In the same way, Fluoropolymer industrial production can and must be handled securely in industrial facilities under controlled circumstances.

- Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report).

- In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:
 - a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
 - b. The key functionalities provided by PFAS for the relevant use.

Application (no finished list)	Use	Property	PFAS	Annual tonnage	Emissions
Valves in Oil and Gas Industry	Gaskets, seals, wear parts in hydrocarbon upstream, midstream and downstream. Fastener coatings in offshore applications	Resistance against hydrocarbons Temperature resistance Low coefficient of friction Corrosion resistance and anti-galling properties	FKM, FFKM PTFE, ETFE	Not known yet	Chemical Industry data
Valves in chemical process industry	Gaskets, seals, wear parts, diaphragm, inserts	Resistance against aggressive chemicals Temperature resistance Low coefficient of friction	FKM, FFKM, PTFE, PVDF, PFA	Not known yet	Chemical Industry data
Valves in food industry	Coatings, seals,	Non-sticking properties Resistance against aggressive cleaning chemicals	PTFE, PFA, FKM	Not known yet	Chemical Industry data
Valves in energy generation (power generation)	Gaskets, seals	High temperature resistance even in the presence of air borne oxygen	FKM, FFKM, PTFE, PFA	Not known yet	Chemical Industry data

Valves in the pharmaceutical and biotechnological industry	Coatings, seals, gaskets, diaphragm	Resistance to high temperatures and aggressive chemicals being used in CIP and SIP	PTFE, PVDF, FKM, FFKM, PFA	Not known yet	Chemical Industry data
Valves in other industries - Wastewater treatment - Dosing - Mining industry - HVAC - Drinking water - Cryogenic applications - H2 production - Environmental mitigations - other	Seals, gaskets, diaphragms, cables, coatings, wear parts, bearings, ...	Resistance against chemicals, temperature, weather, or a combination thereof → Safety Use due to tribologic functionality → energy efficiency, duration, safety Use due to hygienic aspects → health	List to confirm PTFE FKM FFKM FPE (PFPE) ETFE ECTFE PVDF PFA PCTFE	Not known yet	Chemical Industry data
Spare parts for valves	Seals, gaskets, diaphragms, cables, coatings, wear parts, bearings, ...	Resistance against chemicals, temperature, weather, or a combination thereof → Safety. Use due to tribologic functionality → energy efficiency, duration, safety Use due to hygienic aspects → health	List to confirm PTFE FKM FFKM FPE (PFPE) ETFE ECTFE PVDF PFA PCTFE	Not known yet	Chemical Industry data
Sanitary faucets in private and public use	O-rings / seals	Use due to tribologic functionality → energy efficiency, longevity, duration, sustainability	PTFE		Waste water stream / incineration / landfill
Sanitary faucets in private and public use	High performance lubrication grease	Longevity of products, reduction of maintenance and	PTFE - as part of the lubrication grease	100 -1.000 t / a in the EU	<u>Manufacturing:</u> Waste water / incineration / landfill

		repair (exchange of parts), sustainability of products			Use phase: Waste water End-of-life: Incineration / landfill
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c. The number of companies in the sector estimated to be affected by the restriction.

Affected at a large scale (from 30% to 95% of turnover)

Many sanitary faucets and valves will still be sold because they are necessary for managing fluids everywhere, but they won't perform as well as before, earlier failures are to be expected, more maintenance operations mean greater risks for technicians and the environment, changed processes are necessary, and some customers won't be able to sell products (like in the chemical industry), where valves with fluorinated polymer-based advantages are needed.

-Higher total consumer prices must be anticipated (> Total Cost of Ownership) for those industries where less efficient alternatives would be an option, as long and frequent standstill times for maintenance would arise and result in reduced "production capacity" e.g., sanitary facilities in public (airports, train stations, hotels, etc.) and all processes with fluidic installations in all building and industrial sectors).

Alternatives that perform less well put users, employees, and the environment at greater danger. Accidents will happen in particular where insulation materials cannot be used further and no equivalent alternatives are available, for example, in case of leakage (in plants where aggressive, toxic, volatile substances are used)

Compliance with other regulations may be difficult, if not impossible, due to changes in materials or designs, including those pertaining to energy efficiency (Ecodesign, ESPR), reduced carbon footprint targets, renewable energy targets, food contact, drinking water contact, and other regulations. **Main problem to define clear numbers is that the valve industry is less describing the own business, but more the other businesses.**

Information from users of valves and other fluidic equipment is more valuable than that from specialized surveys on the valve industry. Since the procedures of (pre-)suppliers are typically not entirely transparent, it is therefore challenging to define good values with regard to the influence in the upstream supply chain. Actuators, electronics, the creation of materials and components, and other manufacturing processes all depend on PFAS in some way. All of these have an immediate impact on the operation and function of valves.

Sector / Application / Use	Faucet and valves manufacturers either as producer or user	Industrial users/ customers	consumers
	AVR: Brings together 70 of the most qualified and prestigious companies in a sector that in Italy has an aggregate turnover of 7.5 billion euros, with over 60% of exports and a total of 27 thousand employees.		
Building and Industrial valves / Sealing and friction function with high performance in presence of temperature and/or aggressive fluids	Almost all businesses are impacted (even up to 95% of their annual revenue), as valve makers won't produce anything or, in rare situations, may produce under extremely hazardous conditions if suppliers can't provide (even NON-PFAS items).	The use of the valve will have significant effects on the user in terms of process safety, uninterrupted operation of the process, maintenance requirements, worker safety (including during the more frequent maintenance phase), and environmental safety (if a valve malfunctions and has a leak, the hazardous fluid may leak into the environment).	Even though citizens may not prioritize valves (particularly building and industrial valves), they are vital items that affect many activities in the event that the supply chain undergoes significant changes.

- d. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.

PFASs, which are mostly fluorinated polymers, are frequently employed in coatings, hoses, wires, and seals, and there are some reasons why real 1:1 alternatives to these substances are not yet available:

- **Unique performance and properties:** PTFE and FKM offer outstanding performance in terms of chemical resistance, temperature, friction, and wear. These properties are particularly important for high-pressure, high-temperature applications and in aggressive environments where valves and taps are often used. At present, it may be difficult to find alternatives that offer the same unique characteristics as these substances.
- **Cost and availability:** PTFE and FKM are materials widely used in industry and are available in various forms, such as sheets, gaskets, or coatings. Alternatives may not be as affordable or readily available on the market. Introducing new materials would require investment in research and development, manufacturing processes, and testing to ensure that they meet the required performance standards.
- **Regulations and approvals:** Valves and taps used in many industries, such as the chemical or food industries, must meet strict safety and compliance standards. Any alternatives to existing materials must undergo testing and approvals to ensure that they meet these regulatory requirements. This can require considerable time and resources.
- **Long-term reliability and durability:** PTFE and FKM are known for their long-term durability and chemical resistance. Any alternative must demonstrate similar durability and the ability to withstand exposure to harsh chemicals and demanding environmental conditions for an extended period.

While in certain circumstances banning these substances could mean that the performance of products would significantly decline, in the majority of the cases other products may no longer be produced, imported, and put on the market, depriving enterprises of their entire or part of their economic base in the event of a PFAS ban.

For more information see CEIR answer 6598 which is supported by AVR.

e. For cases in which **alternatives are not yet available**, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.

Currently, as already expressed, there are no equivalent alternatives. If an alternative is even found, the engagement of the chemical sector will play a significant role. Even if a design modification is possible, there are several obstacles to overcome. First of all, it takes a lot of time to find a suitable design that performs the desired functions. Second, a prolonged testing process is necessary, particularly when several attributes must be evaluated for qualification. In the majority of trial scenarios, a decline in performance is predicted, prompting an assessment of various strategies. If polymer substitutes are found, the production method will need to be changed. It is necessary to implement novel molding procedures, which calls for the development of new tools (perhaps including PFAS in the lack

of substitute technologies). The time needed for qualification and the related costs significantly increase when replacing a fluoropolymer necessitates the usage of numerous polymers.

For more information see CEIR answer 6598 which is supported by AVR.

f. For cases in which **substitution is technically and economically feasible** but more time is required to substitute:

- i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);
- ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
- iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);
- iv. information on the benefits for alternative providers.

- Where an alternative is available, it is already employed because most consumers do not accept the higher initial material costs associated with using PFAS-containing materials.

-Where fluorinated polymers are utilized, there is no other option because they outperform other material alternatives in terms of life expectancy, functionality (including energy efficiency), and safety (work safety, safe use, tightness, etc.).

-Since decades, the use of fluoropolymers has improved the performance of valves (tightness, durability, energy consumption, temperature range, etc.); the prohibition of PFAS-containing materials used in fluidic equipment will result in a technological and safety regression for users.

- Allow time to improve the current supply chain processes (including end-of-life and actual investigation of prospective alternatives) and to conduct a realistic effect analysis in order to outlaw what truly needs to be outlawed.

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g. For cases in which **substitution is not technically or economically feasible**, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

Valves and taps are used in and/or produced in relation to:

- The creation of (assembled) products - The production of basic chemicals
- The creation of materials, both PFAS- and non-PFAS-containing.
- The production of components, including those made of several materials, such as electronics.
- The creation of machinery for the various production phases.
- Water treatment, particularly the treatment of industrial effluent
- Transportation and energy generation, particularly renewable energy
- Recycling and disposal - Other industrial sectors (pharmaceutical industry, food and feed manufacturing where disinfection is necessary,...)

Both upstream and downstream factors are taken into account when analyzing the impact on the valves and taps industry. It is impossible to quantify the socio-economic effects of the manufacture of valves and taps because of the complex nature of the supply chain in this industry. The entire industry is impacted, and any breakdown in individual supply chain links could result in the wider ecosystem for valves and taps to collapse. Manufacturers in this sector would have trouble finding materials from their supply chains that included both PFAS- and non-PFAS-containing components. Consequently, it would be difficult to produce valves and taps.

It is obvious that the effects of enacting a ban or tight regulations on the use of PFAS stretch far beyond any one industry or market area. By taking such steps, several modern technology in the fields of friction reduction, chemical resistance, heat resistance, environmental effect, product purity, and sealing would essentially be retrogressed to the 1950s. A "by exception" law cannot be implemented practically when more than 10,000 substances are touched, not to mention potentially even more processes and applications. A ban or restriction on PFAS compounds would have enormous negative effects, making significant sectors of the European chemical, pharmaceutical, aerospace, automotive, and other industries noncompetitive in many international markets. The ensuing social and economic repercussions in Europe would be extremely serious and require concerted prevention. Because they are crucial elements of the production process, valves and taps are viewed from the downstream perspective as playing a crucial role across the entire supply chain. They simultaneously buy components, resources, and energy from different supply chain participants, who in turn use valves and taps themselves. As a result of the complex interactions between upstream and downstream components of the valves and taps business, attempting to estimate costs becomes a challenging task. Accurately estimating the financial ramifications is a very difficult task due to the various interactions in this network.

