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CEIR position on PFAS ban proposal in the framework of REACH regulation.

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About CEIR

CEIR, the European Association for the Taps and Valves Industry, formed in 1959, gathers a large number of European manufacturers in the field of valves and fittings. CEIR supports the principles of a free economy and private enterprise in Europe as well as on a global basis. CEIR represents the common economic, technical and scientific interests of the European valve industries, in particular towards international authorities and economic and commercial circles.

According to last statistics, the European taps and valves production value represents more than €11bn and 300 European companies. The European taps and valves industry is divided in 3 branches:

- Industrial valves (€3.73bn production value),
- Sanitary taps and valves (€6.50bn production value),
- Building valves (€930mln production value),

CEIR represents valves and taps country associations from Denmark, Finland, France, Italy, Spain, Sweden, Switzerland, Turkey and United Kingdom and individual companies from Germany as well.

About the PFAS restriction proposal and consultation period

On 7 February 2023, the European Chemicals Agency (ECHA) published the Annex XV REACH restriction report (and annexes) for per- and polyfluoroalkyl substances (PFAS) that has been prepared by 5 Competent Authorities from Denmark, Germany, the Netherlands, Norway, and Sweden. The restriction dossier proposes a near-total ban of all PFAS substances, including fluoropolymers.

CEIR recognizes the public and political concern about PFAS and welcomes the opportunity to provide inputs to the public consultation organized by European Chemicals Agency (ECHA) on the PFAS restriction proposal.

Given the scope of the proposed ban on more than 10,000 PFAS, we believe that a longer consultation period would be beneficial to gather full input from stakeholders, particularly those downstream of PFAS production who incorporate articles into their finished products. It appears that identifying the uses of PFAS in complex supply chains and assessing potential alternatives requires considerable effort. A first review in our industry estimates that the identification process of PFAS would span over 3 years.



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We also stress that the transitional period of 18 months for a ban without derogation or exemption is unrealistic. The design, standardization, validation and certification of complex articles, guaranteeing the availability of safe and durable products, require a realistic timescale. We recommend taking as a reference the 42 months transition period provided for the new Machinery Regulation. Our industry estimates that the testing and validation of alternative substances phase would take between three to five years depending of the applications and equipment; even much more for more difficult cases or without chance to find substitute for many.

More, using the one-ban-fits-all approach on a hugely diverse group of PFAS with varying risk profiles creates a disproportioned burden for a huge portion of the supply chain. According to Plastics Europe's Fluoropolymers Product Group (FPG), various toxicologic profiles of PFAS should be taken into consideration. According to the German association for machinery and equipment manufacturing (VDMA), the global PFAS ban as now planned by the EU due to environmental hazards in the area of consumer products (ski waxes, Teflon pans or outdoor jackets) is both excessive and unfounded. Indeed, according to the OECD, a whole series of PFAS, the so-called "polymers of low concern" pose <u>no</u> danger to the environment. CEIR is aligned with these three positions and is requiring for an actual complete risk-based approach, a responsible manufacturing and an End-of-Life management instead of a total ban.

CEIR also regrets that circular economy aspects such as the availability of spare parts, remanufacturing and the reuse of products, have not been taken in consideration in the proposed restriction project. Present equipment containing PFAS substance have been designed, validated and qualified with them. The lack of recognized alternatives could open the door for regrettable substitution to alternatives that do not perform at the same specification, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety standards.

Moreover, CEIR highlights that PFAS materials are essential for critical and strategical applications for ecological and energetic transition as for technical and industrial independency of Europe without short term alternatives as batteries for EV, water and atmosphere purification, water electrolysis, energy/hydrogen storage, applications in pharmaceutical manufacturing equipment, electronics, aerospace, military & defense, transportation, semiconductor manufacturing and many other high-end niche applications.

Finally, we would draw your attention to the importance of effective market surveillance in preventing the introduction of non-compliant products into the EU. As this draft restriction imposes an obligation of result, the same obligation commits you in terms of market surveillance: robust surveillance mechanisms must be put in place to ensure compliance with the proposed restrictions and adequate resources must be allocated to monitor and verify the presence of PFAS in products and promote a level playing field for all European manufacturers. Including the technical means to assure adequate and effective controls.



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Comment on Valves and Taps sector specific restrictions (see annex)

In valves and taps, PFAS materials are used in a wide range of applications, including but not limited to sealing, bearing, special inserts, coating or lubricants. These materials are chosen due to their exceptional characteristics. It is important to note that PFAS materials are considerably more expensive, up to 100 times, compared to standard materials. Consequently, their application is limited to cases where no viable alternatives exist.

In industrial valves, significant example is cryogenic applications as transfer, transport and storage of liquefied gas as liquid CO2, liquid nitrogen, LNG, liquid helium of liquid hydrogen. Due to exceptional properties at cryogenic temperatures (from -80°C to -253°C), PFAS fluoropolymers (PTFE, PFA, PCTFE) cannot be replaced for the moment by materials having less performant behavior.

In Chemical synthesis including Active Pharmaceutical Ingredient, PFAS fluoropolymers are essential for guaranteeing equipment safety and integrity, preventing gas/liquid emissions, and ensuring adequate lifetime and performance due to their combination of temperature resistance, low coefficient of friction and sealing properties.

For sanitary industry, PFAS fluoropolymers such as PTFE[®] are mainly used for sealants (O-rings) and in the area of high-performance lubricants / greases for fittings. While substitution in the area of sealants is relatively easy, when products are used under "normal" temperature, pressure and climate conditions and has often been implemented already, substitution in the area of high-performance fitting greases and sealants, used in aggressive, hot media or steam is currently not yet possible.

Many other examples are existing to show that PFAS fluoropolymers used in valves and taps have been selected for their specific characteristics and that replacement is not possible without equipment performances/safe use decrease as tightness or equipment redesign and requalification.

Conclusions

CEIR, as the representative body of Europe's valves & taps manufacturers, supports regulations aimed at preventing or reducing the introduction of PFAS into the environment. However, in certain valves and taps applications, the use of PFAS remains essential due to safety, (eco-) efficiency, and functional considerations when handling (hazardous) liquids and gases. As there are currently no alternatives available for these specific applications, the use of PFAS should continue to be permitted to prevent the substitution of PFAS with other hazardous substances not yet assessed, regrettable substitutions against the safeguarding the environment. Of course, new substitution studies may take place in case of identified possible new solutions.

In this context, we advocate for a balanced, proportionate, verified and realistic approach that takes into account the complexity of supply chains, promotes circularity, considers the different risk profiles of PFAS, and allows for sufficient transition periods and exemptions where necessary. We also emphasize the importance of effective market surveillance to ensure regulatory compliance of products and, ultimately, fair competition.



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Finally, **CEIR:**

- → calls upon the Commission and the co-legislators to amend the REACH Regulation in force in order to significantly extend the stakeholder consultation for a minimum of 36 months,
- → calls for a realistic impact analysis and assessment in order to ban what really needs to be banned and let time to improve the current processes along the supply chain (including end of life and actual research of potential alternatives),
- → calls for a minimum five years' transition period and a general exemption from the ban of the fluoropolymers "of low concern" that are proven to be non-hazardous,
- → calls for a stronger regulation on PFAS emissions during fluoropolymers production and a ban of importation in Europe of fluoropolymers coming from regions without PFAS emissions regulations,
- → calls for an End-of-Life regulation concerning fluoropolymers guarantying a complete collection and treatment including all the supply and users' chain,
- → calls for fair trade thanks to an effective market surveillance based in technical means to assure adequate and effective controls.



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Annex: Valves and taps sectorial highlight

1. Importance of valves and taps for health and society

Transport of liquids and gas is fundamental to the smooth operation of life in all aspects. From the central heating and water supply in our homes, sewage and wastewater treatment in our cities, through extraction and processing raw materials to manufacture finished products – valves & taps play a fundamental role quite everywhere. Industrial applications can range from water treatment, food processing, chemical industry, oil & gas, mining, paper mills, fire-fighting, dredging, waste removal and many more. Future applications to help the green transition would include transportation of hydrogen, geo-thermal, and green gases.

Their unmatched chemical resistance, temperature resistance, unique tribological properties and the combination of these characteristics, make PFAS containing materials irreplaceable. No currently available alternative material guarantees the same performance, safety and lifetime.

For example, due to exceptional properties at cryogenic temperatures, PFAS (PTFE, PFA, PCTFE) are also critical for equipment that import, handle and store liquefied gas, such as liquefied natural gas or liquified hydrogen. The former is critical for supplying gas with LNG tankers to replace Russian gas, and the latter is a potential future energy supply solution.

At these cryogenic temperatures (-161°C for liquid methane gas, -253°C for liquid hydrogen) no other elastomeric materials are adequate and even metallic materials have not the same performance. Other materials such as PVDF are critical in applications where aggressive chemicals are dosed and handled. Due to the combination of temperature resistance, low coefficient of friction and sealing properties, PFAS are essential for guaranteeing equipment safety and integrity, preventing gas or liquid emissions, and ensuring adequate long lifetime and high performance.

The challenge of lack of PFAS-free alternatives for essential use is not limited to valves applications. It equally applies to other equipment like pumps, compressors and downstream industries like pharma, chemicals, petrochemicals, and aerospace. Furthermore, electronic components are also critical for valves and some electronic equipment require the use of PFAS materials to ensure safety. A lot of valves cannot function without these electronics.

2. PFAS in valves & taps applications.

As a result of their exceptional properties and performance, including thermal and chemical resistance, as well as friction properties and abrasion and wear resistance, PFAS materials are employed in valves and taps to enhance functionality and achieve superior levels of performance and safety. Since years, these materials have extended the service life of components and products, reduced maintenance intervals and thereby improving overall resource efficiency and product sustainability.

It is important to note that the cost of PFAS materials varies significantly, ranging from 2.5 times to nearly 100 times the price of standard materials. Consequently, there is a commercial regulatory mechanism in place that restricts the use of PFAS materials in valves and taps applications to cases where their implementation is necessary for reasons of safety or performance. As an example, from one of our members, manufacturer of ball valves: "PFAS fluoropolymers are representing less than 5% in weight of our products but are used in 95% of our equipment!"



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Exceptional properties and performance: examples

Valve and faucet producers in the EU demand up to 200,000 load cycles in its own continuous test laboratories, which translates to a service life of about 20 years. Currently, these requirements can only be met by the high-performance fitting greases in which PTFE (e.g., Teflon[®]) is used.

Trials with alternative materials have been underway for more than 2 years, all of which have so far failed to meet the required continuous serviceability (in the form of the required 200,000 load cycles).

Since corresponding alternative materials are currently not available, any restriction of fluoropolymers such as PTFE (e.g., Teflon[®]) would represent significant deterioration for the long-term serviceability and sustainability of sanitary fittings.

For industrial valves, a concrete example is the difference we can state between soft seals (fluoropolymers) and metallic seals. Metallic seals may be a substitution for fluoropolymer seals but when you obtain a tightness level class A (zero leakage) with a PTFE seal, the class is B, C and even D for a metallic one (leakage at different rates) (ref. EN 12266 or ISO 5208).

In this context, CEIR stands in support of regulations aimed at preventing the release of PFAS into the natural environment and safeguarding human health. However, implementing a comprehensive ban on PFAS would have adverse consequences. Such a ban would lead to increased environmental pollution through emissions and/or leakages, as well as reduced performance (resulting in diminished energy efficiency), durability, safety, and overall resource efficiency, as such questioning other EU strategic objectives like the EU-Green Deal, longevity/durability, circularity and sustainability of products.

Instead of adopting a hazard-based approach, regulations should be proportionate and reflect a riskbased approach that must be professionally established. This means considering the specific risks associated with PFAS materials and their applications including comparison with possible substitutes, rather than implementing a blanket ban that fails to account for nuanced factors.



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3. Essential functionalities in valves and taps



3.1 Sealing

In valves and taps, PFAS materials are primarily utilized in sealing applications, specifically in seals, Orings, and gaskets. Due to their considerable cost, ranging from 2.5 times to nearly 100 times that of other natural or synthetic elastomers, the usage of PFAS materials is limited to absolutely necessary, and when there are no suitable elastomeric alternatives available.

The primary advantage of PFAS containing elastomers/polymers is their exceptional chemical resistance to highly aggressive liquids, where standard elastomers/polymers would quickly deteriorate. Additionally, PFAS elastomers/polymers can maintain their elasticity and sealing properties at temperatures where other standard elastomers/polymers would harden, often within a few hours or days of use, rendering them incapable of providing an effective seal. For example, in industrial ball valves, hight density polyethylene (Non PFAS) is limited to 100°C and for non-hydrocarbon fluids so for steam circuits or for petrol-based fluids, it cannot be used.

PFAS seals are primarily, although not exclusively, used in industries such as chemical and petrochemical, where leakage in valve and taps, seals could lead to the exposure of operating personnel, equipment, and the environment to hazardous, corrosive or toxic chemicals. They are also employed in industries like pharmaceuticals, where the presence of elastomeric/polymeric seal residue in the process liquid can cause process disruptions and raise safety concerns related to the final product. Furthermore, apart from addressing leakage issues, attempting to use non-PFAS materials when PFAS is necessary would significantly increase the requirements for service, including disassembly and replacement of seals or components. This would result in additional exposure of maintenance personnel to hazardous, corrosive or toxic process fluids.

For more in-depth technical information, the European Sealing Association (ESA) has produced a position paper titled "European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry." This position paper can be found and downloaded from the ESA website: <u>www.europeansealing.com/about-us/position-statements/</u>. CEIR supports that document.



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Another application of fluoropolymers is for the ultrapure water and gases process that is used for semiconductors manufacturing. The exceptional quality of PTFE in term of stability and no pollution of the water that must be ultrapure in order to not pollute the sensitive electronic components is demonstrating the inexistent risk of emission/diffusion in the fluid. Fluoropolymers such as PTFE or similar are stable and clean.

3.2 Bearings

Most bearings that incorporate PFAS are constructed using PTFE (polytetrafluoroethylene) and are employed in situations where standard metal bearings are not viable due to high coefficients of friction, or where other polymer bearings fail under high loads or temperatures. PTFE, unlike other fluoropolymers, does not melt, exhibits an exceptionally low coefficient of friction, possesses self-lubricating characteristics, demonstrates resistance against nearly all chemicals, and can operate within a broad temperature range. These properties make PTFE an ideal material for applications involving limited lubrication, aggressive chemicals, and high temperatures.

In many bearing applications, PTFE is not used in its pure form but is instead filled with materials such as glass fiber, graphite or other inert substances to expand its range of applications. While unmodified PTFE can withstand an effort or a constraint of only 1.000 (as a reference), filled PTFE can handle values exceeding 10.000 or even higher, surpassing the capabilities of most commonly used bearing materials. The positive consequences are higher durability of the valve and also possibility to reduce the dimension of the bearing and weight of the valve.

PTFE bushing-type bearings offer the advantage of dry-running capability in scenarios where lubrication is limited or not feasible due to environmental or hygienic constraints, and where heat build-up from friction is a concern. An example of the use of these PTFE bearings is for pure and dry gas valves for electronics. In these dry fluids, experiments carried out by some of our members show lifetimes of 10 to 100 times longer for PTFE bearings compared to alternative materials without PFAS.

Due to PTFE's extremely low coefficient of friction against metallic shaft materials, the utilization of bearings containing PTFE contributes to friction loss reduction, leading to energy savings which is a main concern for the environment. Additionally, PTFE-based bearings are essential in applications where metal bearings may corrode and non-PFAS polymers may swell, compromising their mechanical and tribological properties.

PTFE does not require the use of processing aids like stabilizers to prevent thermal degradation or plasticizers to enhance elasticity, as it is typically required for other materials. Its inherent stability and lack of additives ensure that no foreign substances are leached into the fluid flowing through the bearing. For this reason, PTFE-based bearings are also preferred in food and beverage processing plants, where other materials may degrade over time and release potentially harmful substances into the process.

Considering the very low coefficient of friction, which leads to minimal wear and extended service life, the environmental impact of PFAS-based bearings in valves and taps applications is rated as very low. At present, complete substitution based on existing technological capabilities is not feasible and may introduce concerns related to environmental and sustainability impact.