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**RELegend:** *italic* – original wording of questions from ECHA; regular – wording from HE’s position paper (published in January 2023); **red** – new wording, added for the consultation (based on input gathering in 2023)

**As the ECHA website only allows for simple text input, the figures will be included as an annex, while the footnotes will be added to the end of each part. This document does not have the annex for confidentiality reasons.**

**SECTION III. Non-confidential comments**

*It is possible to provide both general comments on the Annex XV restriction report subject to this Consultation and answers to the specific questions posed. In both cases, it is necessary to provide supporting evidence to allow ECHA’s Committees to take your comments into account. It is important not to leave the submission of any socio-economic information until the consultation on SEACs opinion but already submit relevant comments at this stage.*

*General Comments*

*Select the relevant boxes that cover the content of your comments and provide your non-confidential comments below, (maximum 9 000 characters)*

Scope or restriction option analysis
Hazard or exposure
Environmental emissions
Baseline
Description of analytical methods
Information on alternatives
Information on benefits
Other socio economic analysis (SEA) issues
Transitional period
Request for exemption

*\* I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, email addresses, phone numbers, signatures etc.). ECHA will not be held liable for any damages caused by making non confidential responses publicly available.*

**Please provide your general comments in the box below (max 9000 characters)**

The European Sealing Association (ESA) represents most Sealing Device manufacturers in Europe. The ESA has over 50 members, with a combined turnover of 2.6 billion euros, and employs some 12,500

people. PFAS are critical to global industry in their use as sealing elements. Sealing devices and materials – which perform a crucial role in the safe containment of fluids – are employed in a wide cross-section of business, including: mineral extraction, chemical and petrochemical, power generation (e.g. nuclear sector) and supply, automotive, aerospace, marine, potable and waste water, valve, pulp & paper, pharmaceuticals, food & beverage, refrigeration and compression. The ESA is requesting the ECHA to consider an exemption (or unlimited derogation) allowing the manufacturing, distribution and use of fluoropolymers in the sealing industry and/or its end-sectors.

The ESA is currently preparing a socio-economic analysis (SEA) with an independent consulting agency, providing tangible and unbiased data to Regulators regarding the importance of the sealing industry for the EU economy and the current status/use of non-PFAS alternatives. Results will be sent to ECHA in another submission as soon as they become available.

The restriction proposal's approach to group together all fluoropolymers with other PFAS types must be revisited. Henry et al. (2018) in the Integrated Environmental Assessment and Management (2018)<sup>1</sup> and Korzeniowski et al. (2022)<sup>2</sup> demonstrated that the vast majority of fluoropolymers meet the OECD criteria to be defined as 'polymers of low concern' (PLC). They verifiably do not pose a risk to human health or the environment as they do not dissolve or contaminate water, are not found in drinking water, and cannot enter or accumulate in a person's bloodstream. It is worth noting that the UK government decided to exclude fluoropolymers, along with other lower concern groups of chemicals, from its upcoming PFAS restriction proposal.

Instead of an outright ban on the use of fluoropolymers, the restriction should focus on substances that present an unacceptable risk in line with REACH regulation, and for which alternatives may be available. For exempted uses, legislators should set up a framework incentivising a) best practices for the manufacturing, use and end-of-life stages of fluoropolymers, implementing circular economy practices across value chains (closed circle with take-back system implementation and recycling/reuse at disposal stage) in the short and medium term, and b) research into finding substances (whether fluorinated or not) that could at minimum reach or ideally even surpass the same KPIs as those currently used fluoropolymers offer (considering quality, durability, efficiency, physical and chemical properties, economic viability) in the medium to long term.

Fluoropolymers are substances of low concern however current global practice to manufacture fluoropolymers uses fluorinated PFAS processing aids, all of which are PFAS surfactants. PFAS surfactants are water soluble, surface active and bioavailable therefore should be regulated at the earliest opportunity however manufacturing processes to make fluoropolymers without these PFAS surfactant is immature or unproven. Some fluoropolymer manufacturers have undertaken development and communicated their intent to adopt manufacturing process that does not use PFAS surfactant. Evidence exists that manufacture of PTFE and FKM is possible without PFAS surfactants but

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<sup>1</sup> Henry et al. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Integrated Environmental Assessment and Management published by Wiley Periodicals, Inc. on behalf of Society of Environmental Toxicology & Chemistry (SETAC), Volume 14, Number 3, pp. 316-334. Retrieved on: <https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4035>.

<sup>2</sup> Korzeniowski, S.H., et al. (2022), A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag.

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other fluoropolymer material types have not been demonstrated even at laboratory scale. In addition, it is important to note that PFAS surfactants are used in the production of non-PFAS polymers that have been identified as theoretical substitutes to PFAS polymers in sealing.

Fluoropolymers manufactured from processes without PFAS surfactant will differ from those conventionally made with PFAS surfactants which may impact both mechanical and chemical properties. For the critical applications in sealing where fluoropolymers are used this will necessitate a full material and product requalification for every application. The time required to undertake requalification is extensive.

Therefore we would recommend to ECHA granting a longer transition time (e.g. 12 years) for the use of PFAS surfactants for the production of fluoropolymers until non PFAS processing aids have been identified and demonstrated in production. We would like to remind ECHA that PFAS surfactant are only used at the fluoropolymer manufacturing location.

It should be noted that investor and community pressure is already incentivising or demanding polymer manufacturers to seek alternatives to PFAS surfactants and therefore there is no need for a shorter derogation to drive changes in the polymer supply chain.

Regarding the timeline for implementing non-PFAS alternatives, current derogation timeframes do not provide us with enough time to develop new materials and ensure non-PFAS alternatives will not cause long-term adverse environmental and/or health effects. As per the [report](#) published by the White House (Executive Office of the President of the United States) in March 2023 “Many challenges remain to identifying cost-effective, safer, and environmentally-friendly alternatives, while still avoiding substitution regret”. This cannot be done for sealing devices by 2027, and in many cases, the 5- to 12-year derogations proposed in some end-sectors might also not be sufficient to safely develop and deploy those alternatives. When it comes to seals, it is important to have in mind that some manufacturers provide technologically advanced sealing systems that are installed in extremely harsh environments (e.g. space shuttles, hydrogen liquefaction facilities, etc). Those applications cannot be compared to more basic seals for which non-PFAS alternatives, even if non-optimal, would have a more limited industrial or safety impact if they are introduced.

From a more operational perspective, the ESA regrets that product lifecycles were not considered in terms of the necessity to use PFAS-containing spare parts to repair and maintain existing devices. While mechanical seals can be refurbished, there is no direct replacement for PTFE that will meet the same compressibility requirements. PTFE has a Young’s Modulus of 0.4 – 0.8. No other high performance or ultra-high performance non PFAS-containing polymer is as compressible or suitable for use in most harsh chemical environments. Therefore, the current proposal exposes the EU with a risk of not being able to maintain mission-critical equipment (seals, pumps, compressors, etc.) deployed in nearly all industrial sectors, which causes an important threat to the EU economy. In addition to the above, derogation timeframes also need to be aligned with lifecycle timeframes to avoid warranty issues.

On a similar note, the ESA is concerned that the interlink between sectors does not seem to be taken into account in the proposal. In particular, electronic components are largely used within the Sealing industry (e.g. monitoring systems, sensors.) and are not derogated. For instance, seals sold into the oil & gas industry (12-year derogation) often include seal support systems which include electronics (no derogation). These seal support systems are mission critical flow control solutions designed to increase

efficiency, reduce emissions and promote energy transformation. Electronic components are typically integrated into complex devices or systems. Therefore, even if the sealing sector were to get a derogation, the absence of derogation for electronics may still result in major disruptions both for our own operations and within the end-sectors we serve. Indeed, some electronics-containing devices may not be produced and/or repaired until a PFAS-free alternative is developed, which could take several years. In light of the above, we consider that if a derogation is granted for a given sector (e.g. petroleum and mining), then it should cover all components needed to safely continue operations regardless of each individual component's market sector. At a minimum, more clarifications on those aspects should be included in the restriction proposal.

To conclude, in light of the low risk profile of fluoropolymers, the lack of alternative available in a particularly demanding industrial environment, and the socio-economic impact the current proposal would have on the European society, we believe appropriate for the ECHA to consider an exemption (or unlimited derogation) allowing the use of fluoropolymers in the sealing industry.

***7: Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.***

***A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.***

***To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.***

**12-year derogation for reconsideration on transport for the applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods.** The ESA welcomes to ECHA's intention to consider the transport sector as a whole in the restriction. Nonetheless, much more details are required to clarify the scope of this derogation in order for the industry to provide appropriate comments. For now, this definition is very ambiguous regarding its applicability to sealing devices and thus we are unable to determine with certainty the impact of this derogation on our products. In addition, this 12-year derogation does not seem sufficient to cover specific applications such as aerospace. In this particularly high-tech and heavily regulated environment, finding and deploying safe alternatives to fluoropolymers will take much longer. For reference, aerospace is taking 32 years to develop an alternative to Hexavalent Chromium and obtain approval. With no known suitable replacements for PTFE and given the number of critical applications

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it covers, it is fair to conclude that phasing out those substances may take a similar amount of time, if not longer.

### **12-year derogation for reconsideration on the semiconductor manufacturing process:**

ESA welcomes this derogation proposal. However, as mentioned in our general comments, further clarifications are needed when it comes to the interactions between the electronics (not derogated) and the semiconductor sector (for which this proposed derogation applies). In practice, it is not clear how this derogation would apply, if PFAS-containing electronics components are not derogated. In any case, it is very unlikely that alternatives will be available by 2027 for all PFAS-containing components used in the semiconductors manufacturing process.

***8: Other identified uses – Analysis of alternatives and socio-economic analysis: Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.***

***For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.***

***More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.***

### **Sealing devices**

ESA regrets that sealing devices were not listed in the restriction proposal, despite its mission critical applications in most EU key industrial sectors. We would like to reiterate that sealing devices using fluoropolymers (fluoroplastics, fluoroelastomers) are irreplaceable in certain industries as they ensure the safety and reliability of processing involving gases, liquids and powders. Our members use fluoropolymers to meet extreme operating conditions (heat, corrosion, pressure, etc.) without which our devices could not guarantee the safety and reliability of industrial infrastructures. The same applies to the safety of equipment operators in chemical plants, wastewater treatment operators, pulp and paper processors, service technicians, airline passengers, pilots, astronauts, vehicle operators, train drivers, etc. In addition, many of our end-sectors are heavily regulated (e.g. aerospace, pharmaceuticals, etc.) which make any design changes subject to years long testing and approval

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processes. Other processes will also require a long time to be updated (e.g. design drawings, equipment modifications, etc.). Finally, there is also customer mandated testing – PPAP (Production Part Approval Process) – whenever a major design change is required. This alone typically takes up to 1 year. In some sensitive environments like nuclear power plant, the PPAP can even take more than 5 years.

Another critical issue not tackled in the proposal concerns spare parts. Sealing devices typically undergo regular repair cycles – sometimes carried out by the seal manufacturer - to ensure the reliability and durability of the equipment. Under the proposed ban, producing, procuring, or selling any PFAS-containing spare parts would not be possible as of 2026-2027. This situation would have a very detrimental impact to our industry and its end-sectors for three reasons. First, it would make repair and maintenance operations extremely difficult, or in many cases virtually impossible. Second, it would directly affect the safety of industrial operations, as existing systems would get much harder to repair. Even where a sectoral derogation applies (e.g. O&G) the ban may still make it challenging for the industry to procure needed spare parts. Third, the ban would add a high level of uncertainty to existing warranty and maintenance & repair contracts. Therefore, ESA believes that it is crucial for the ECHA to ensure the proposal would not affect maintenance and repair operations. We also recommend the ECHA to ensure time-limited derogations take into account the equipment's life cycles.

Finally, the ESA would like to highlight that sealing devices are critical components for the EU to reach its GHG reduction objectives and achieve the Green Deal. For instance, our industry plays a key role in increasing the efficiency of energy and industrial infrastructures, as well as preventing methane and CO2 leakages. As a reminder, sealing devices are also critical to green technologies such as CCUS (Carbon Capture, Usage and Storage) and Hydrogen. Looking ahead, we believe all available technologies—CCUS, hydrogen, nuclear, solar, wind, hydroelectric, geothermal—and significant global investment will be required to achieve net carbon neutrality and stay below 1.5°C warming. As such, the sealing industry is innovating to deliver a broad range of novel technology and services addressing new customer needs related to those new energies and their complex applications. The current restriction proposal brings a lot of uncertainty to our members as there is currently no visibility on whether our upcoming products will be allowed to be placed in the EEA market.

Considering the transversal use of sealing devices across a very high number of key industries, we believe it is appropriate for the ECHA to address the sealing devices as a specific sector within the restriction dossier. Indeed, relying on derogations granted to some of our end-sectors would usually not reflect the importance of our products and our uses of fluoropolymers. It would also make it extremely difficult for our members to operate due to the complexity of navigating a patchwork of different restrictions across the myriad of end-sectors we serve. In addition, as mentioned in our general comments, we consider that an exemption for the use of fluoropolymers covering the sealings industry would be justified, given its impact on the EU economy and the absence of current alternatives. We will be providing more details on these points once the result of our SEA becomes available.

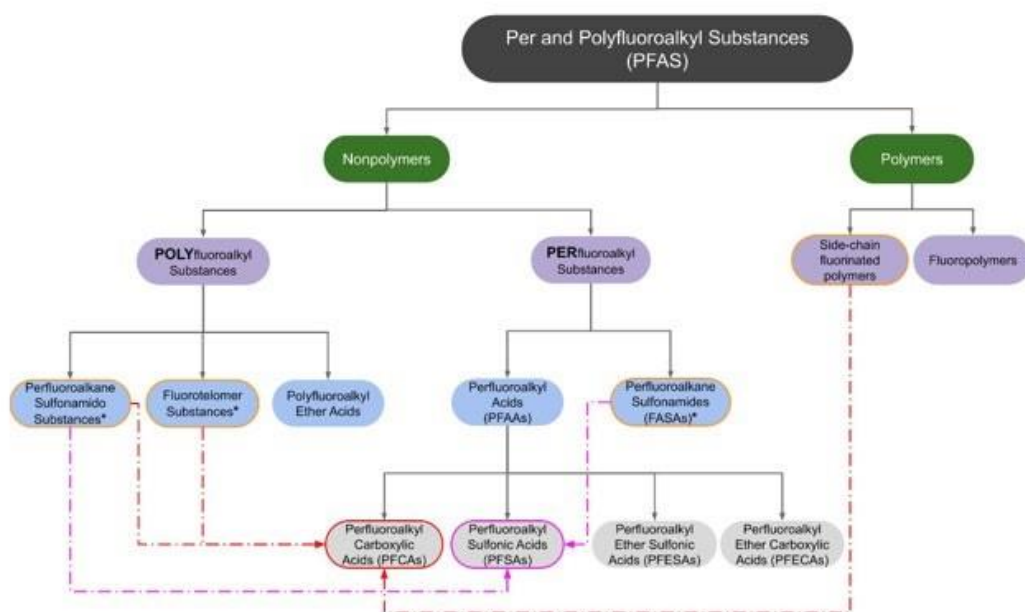
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#### SECTION IV. Non-confidential attachment

If needed, attach additional non-confidential information (data available in excel format, reports, etc.) below. Do not attach the same information already provided in section III here. If part of the information is confidential, please use section V to share it

Add attachment

### PFAS Basics: PFAS Tree Pathways with Transformation Pathways Identified



If you would like to submit more than one document, please create a compressed archive where you include all files and upload the compressed file as attachment. Maximum file size is 20 MB.

**\* I have removed/blanked the information I wish to keep/I have claimed confidential from all the attachments in section IV (e.g.: company name, company logo, personal names, email, signatures, other confidential business data).** I understand that ECHA will not be held liable for any damages caused by making the attachments publicly available.

#### SECTION V. Confidential Attachment

If needed, attach confidential information below (for example: studies, laboratory tests, additional contact details, business data, etc.). Do not add the same information already provided in the previous

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sections here. Confidential information will only be used by ECHA, including its Committees, by the Member State competent authorities and by the European Commission.

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