**General comments and answers to specific information requests**

**Specific information requests:**

1. **Sectors and (sub-)uses**: Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.
2. **Emissions in the end-of-life phase**: The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:
3. Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.
4. If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.
5. **Emissions in the end-of-life phase**: With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.
6. **Impacts on the recycling industry**: To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:
7. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).
8. The measures that recyclers would need to take to achieve the proposed concentration limits.
9. The costs associated with these measures.
10. **Proposed derogations – Tonnage and emissions**: 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 proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.
11. **Missing uses – Analysis of alternatives and socio-economic analysis**: 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:
12. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
13. The key functionalities provided by PFAS for the relevant use.
14. The number of companies in the sector estimated to be affected by the restriction.
15. 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.
16. 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.
17. For cases in which **substitution is technically and economically feasible** but more time is required to substitute:
    1. 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);
    2. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
    3. 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);
    4. information on the benefits for alternative providers.
18. 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.
19. **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.

1. **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.

1. **Degradation potential of specific PFAS sub-groups**: A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.
2. **Analytical methods**: Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

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| 8724 | Date:  2023/09/22 15:33  Content:  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  CERAFILTEC  Org. country:  Germany | General Comments:  Winning the War against PFAS: A Path to a PFAS-Free Future with Ceramic Membranes  CERAFILTEC applauds the position of the European Chemicals Agency (ECHA) with regards to restricting all PFAS in all applications in the EU. As a major player in the water and wastewater treatment industry and developer of ceramic flat membrane technology, CERAFILTEC is keenly aware of the deleterious and “forever” issues associated with PFAS and widely used polymeric membranes. As fellow humans, we are—and should be—committed to winning the war against PFAS and their potentially devastating effect on human and environmental health. Much has been written about the dangers of PFAS, and as the world becomes increasingly aware of the environmental and health impacts of industrial materials, the mounting concerns surrounding the PFAS issue cannot be ignored. We stand with our colleagues at the ECHA in waging an important war against these materials. And every battle, no matter how small, is important to our winning this ‘good fight.’ For this reason, we feel compelled to enlighten the ECHA about the available alternative to PVDF membranes used for water and wastewater filtration. The dawn of a new era For those of us in the water industry, the dawn of a new era is upon us—one illuminated by the superior, sustainable and inescapable promise of ceramic membranes. There was a time, not too long ago, when doctors described cigarette smoking as harmless, and wearing seatbelts in cars was seen as an overcautious act. In hindsight, these notions seem ludicrous, even dangerous. Today, with our evolved understanding, we recognize these once-accepted practices as harmful and recognize PFAS as a class of molecules that are serious environmental contaminants. Just as the world transitioned from the soot-stained era of coal to the clean, boundless promise of renewable energy, from the rattle and hum of diesel trains to the smooth, whisper-like glide of electric engines, and from the energy-intensive process of thermal desalination to the sleek efficiency of reverse osmosis, so too is the shift from polymeric UF membranes to ceramic UF membranes underway. Thus transition is not a matter of 'if', but 'how soon'. Ceramic membranes are more than an 'alternative'; they are a leap forward in membrane technology. These innovative solutions are fully capable of replacing polymeric membranes entirely. And as demand increases, the resulting economies of scale will lead to cost advantages for ceramics that are unparalleled and unimaginable. This shift is already happening today, as ceramic membranes are already fully cost competitive. We believe that the scale will continue to tip even more in favor of ceramic membranes, not only for providing more cost-effective solutions for industry participants, but also myriad benefits for sustainability and technical superiority. Advantages of ceramic membranes Ceramic membranes come with a raft of advantages. At the top of this list is the fact that they present no PFAS issue and in fact, are capable of removing PFAS from water with proper process solutions. Clay, silica, and alumina constitute materials from which ceramic membranes are typically made. The sustainable sourcing of these materials reduces the environmental footprint associated with membrane production. They are sustainable, known for their durability and long lifespan, and they produce minimal to no waste. Highly resistant to chemical degradation, they are suitable for treating water and wastewater containing aggressive chemicals or high levels of contaminants and reducing the need for chemical pretreatment or the use of additional chemicals, which also can have environmental implications. At their end-of-life, ceramic membranes can be reused or recycled, a testament to their environmental virtues. In addition, the potential for waste reduction is enormous. If we replaced all polymeric membranes with ceramic ones, we would save plastic waste equivalent to 3 billion plastic bottles annually. Imagine these bottles spread out on the ground, occupying an area of 7,000 football fields—year after year. A transition to ceramic membranes could render this haunting scenario obsolete. Summary Historically, regulations or consumer shifts have led to the replacement of harmful or outdated products with safer, more efficient alternatives. We've bid farewell to lead-based paints, moved beyond the era of ozone-depleting CFCs in aerosols, and replaced single-use plastic bags with reusable shopping bags. Each shift, though initially challenging, brought with it enormous benefits, making it difficult to fathom why we ever persisted with older methods. In the same vein, it will soon be unimaginable that we ever used anything but ceramic membranes in filtration systems. The transition we are discussing is not just about reducing waste or eliminating a potential source of PFAS contamination; it is about embracing progress. It is about acknowledging the inherent human drive to innovate, to strive for better—more efficient, less harmful solutions—that will help win the war against PFAS.  About the Author Julius Glöckner, MBA, CPA, CIA, CFE, is Chief Commercial Officer of CERAFILTEC. He can be reached at julius@cerafiltec.com. |

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| 8725 | Date:  2023/09/22 15:35  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Aspen Oss B.V.  Org. country:  Netherlands  Attachment:  <redacted>  Privacy statement:  Protection of commercial interests would be undermined. | General Comments:  Based on the information presented we propose a derogation for the use of PFASs in the synthesis of active pharmaceutic ingredients. Taking into consideration the manufacturing of APIs is specifically regulated in the EU with extensive evaluations and approval processes by designated bodies with specific expertise and experience. Including the use of PFASs in a highly controlled manufacturing environment. Whereas it should also be noted a restriction on the use of PFASs would have a negative impact on the availability and security of supply of medicines and their future alternatives |
| Answer to specific info request 3:  Enclosed in confidential attachment. |
| Answer to specific info request 6:  Enclosed in confidential attachment. |

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| 8726 | Date:  2023/09/22 15:35  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Groupement Plasturgie Automobile (GPA)  Org. country:  France | General Comments:  GPA is a professional organization that represents french plastic partsmakers. They design and manufacture components, modules and systems in plastic and composite for the automotive industry.  GPA position on the PFAS Restriction proposal is aligned with: - The ACEA submission (submission 4276 of May 2023). - The EuPC submission (submission 6202 of July 2023).  Some explanations on fluoropolymers used in the automotive industry. Fluoropolymers are technical polymers that exhibit a unique combination of properties not found in other materials.  - Thermal stability - Electrical insulation - Low friction - Self-flame retardant - Resistance to chemicals - Durability  Fluoropolymers are used for several key technical components, such as gaskets, hoses, joints, O-rings, seals, cords, cables, or sleeves, …  The current restriction proposal, published on 7th February 2023 will restrict more than 10,000 substances, with vastly differing hazard properties. Fluoropolymers fit the structural definition of PFAS, but have significantly different physical, chemical, environmental and toxicological properties when compared to other PFASs  A REACH restriction requires to demonstrate an “unacceptable risk”.  According to available data, fluoropolymers do meet the standard. The OECD classifies polymers with “insignificant environmental and human health impacts” as polymers of low concern and fluoropolymers have been found to meet all of the OECD characteristics of polymers of low concern, based on their stability, lack of bioavailability, lack of bioaccumula-tion, and general absence of observed ill effects (cf. Henry, Barbara J, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed, and Oscar Hernandez. 2018. “A Critical Review of the Application of Polymer of Low Concern  and Regulatory Criteria to Fluoropolymers.” Integrated Environmental Assessment and Management 14 (3): 316–34. https://doi.org/10.1002/ieam.4035).  Therefore Fluoropolymers should not be considered in this restriction. Substances used solely in industrial settings should be derogated with appropriate risk management measures at manufacturing plant level if appropriate. |
| Answer to specific info request 1:  There are many automotive applications based on fluoropolymer. more than 10 polymers concerned. more than 150 parts concerned, for more than 260 applications. • Fuel Systems : o Seals: FPM, FVMQ o Tubes: ETFE, FEP, PVDF, o Sleeves: F-TPV, FPM, THV o Reservoir (fluoridation treatment) • Bearing o Bearing cage + PTFE bearing,… • Part under engine hood • Hydrogen tank storage systems • Li-ion batteries • … |

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| 8727 | Date:  2023/09/22 15:35  Content:  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  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Garlock GmbH, Falkenweg1, 41468 Neuss  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  Answers to question 10 does list confidential information from other nations and states. Please exclude from open public sharing. | General Comments:  See Uploaded file: GARLOCK PFAS KONSULTATION final questions overall comments #EN\_EU\_KU26223 |
| Answer to specific info request 1:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 1#EN\_EU\_KU26223 |
| Answer to specific info request 2:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 2#EN\_EU\_KU26223 |
| Answer to specific info request 3:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 3 and 4#EN\_EU\_KU26223 |
| Answer to specific info request 4:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 3 and 4#EN\_EU\_KU26223 |
| Answer to specific info request 5:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 5#EN\_EU\_KU26223 |
| Answer to specific info request 6:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 6#EN\_EU\_KU26223 |
| Answer to specific info request 7:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 7#EN\_EU\_KU26223 |
| Answer to specific info request 8:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 8#EN\_EU\_KU26223 |
| Answer to specific info request 9:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 9#EN\_EU\_KU26223 |
| Answer to specific info request 10:  See Uploaded file: GARLOCK PFAS KONSULTATION final question 10#EN\_EU\_KU26223 PLEASE RATE THIS UPLOAD TO BE CONFIDENTIAL and not for open Public |

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| 8728 | Date:  2023/09/22 15:35  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  GIFAS (Groupement des Industries Françaises Aéronautiques et Spatiales)  Org. country:  France | General Comments:  GIFAS (Groupement des Industries Françaises Aéronautiques et Spatiales) is the structure that represents the French aerospace industry. GIFAS has more than 450 members, from major prime contractors and system suppliers to small specialist companies and start-ups. They cover the full spectrum of skills from the design, development and production of aerospace systems to marketing and maintenance and operation. GIFAS members are active in all sectors of the aerospace industry including civil and military aircraft, helicopters, engines, missiles and weapons, satellites and launch systems, UAV, large aerospace, defence and security systems, equipment, subassemblies and associated software applications. The French aerospace industry is internationally renowned which enjoys a leading position in every market segment (passenger planes, business aircraft, helicopters, military aviation, space and defense). Turnover for the French Aerospace Industry: €62,7 billion in 2022; Export: 83%; 195.000 direct employees.  We note that uses by the aerospace sector have not been considered by the dossier submitters in the frame of this restriction proposal for Per- and polyfluoroalkyl substances (PFAS). The proposed restriction (restriction option 2 (RO2)) was developed without taking the specificities of our sector into account. The restriction as currently proposed would have a catastrophic impact as it would bring our sector to a standstill (no production, no imports, no maintenance) already 18 months after the entry into force. The specificities of our sector need to be considered in the PFAS restriction options proposed by the dossier submitters. This is why Gifas, through its European association ASD (Aerospace, Security and Defence Industries Association of Europe), has been heavily involved in the response to this consultation. We therefore support and endorse the response submitted by ASD in the frame of this consultation. ASD is representing directly or indirectly (through national association members) over 3,000 companies of all sizes from 18 countries. We ask the dossier submitters to consider the following : • The formal quality management systems and in particular the strict certification process that are in place to ensure safety and reliability of aerospace products (e.g. AS9100, NATO standards); • The absence of alternatives that can fulfil the performance requirements that underpin the safety and reliability of aerospace products; • The formal change management process in place to ensure safety and reliability of aerospace products mean that substitution is in general lengthy. It could take decades for a full phase out if suitable alternatives could even be developed; • The scale of the R&D activities as a result of substitution needs that would be triggered by a restriction with the current broad scope, • The complexity of aerospace products that are assembled from 10000’s of parts, components, systems etc. provided via multi-tiered global supply chains; • The interdependencies of parts, components, systems, etc. across diverse products mean that the lack of a qualified part can impact products that operate in different market segments (e.g. seals in gas turbine engines where the engines are used in civilian and non-civilian applications); • A shortage of even a limited number of parts/components will mean the product cannot be produced/operated/serviced meaning that derogation coverage must ensure availability of all parts/components over the entire service life of the product; • A 12-year derogation period is not adequate due to the absence of alternatives, the need to develop new chemicals/materials/formulations and the lengthy substitution process to take suitable alternatives into use for both new and existing products; • A review clause through innovation would always be necessary for derogations as there are no alternatives and the timelines needed for the identification, commercialisation and industrialisation of new chemicals/materials/parts/formulations is unknown; • The ubiquity of fluoropolymers in the seals, sealants, cabling, coatings, hosing, etc. across all the parts, components, systems that make up aerospace products and lack of foreseen alternatives to these materials, that do not also possess ‘persistent’ properties (fluoropolymers are often used for their durability/resilience); • Any reporting requirement of uses relying on derogations would need to consider the administrative burden and allow adequate time to collect the enormous volume of information on all PFAS chemicals in complex aerospace products . Specifically we ask the dossier submitters to : • Exclude fluoropolymers (and the precursor PFAS chemicals necessary for their manufacture) from the scope of the restriction given their ubiquity in aerospace products and the absence of alternatives that fulfil the performance requirements for reliability and safety; • Include a sector derogation for the use of non-polymeric PFAS chemicals necessary for the production and operation of aerospace products with a review clause to allow for an extension/renewal of the derogation if needed due to the non-availability of suitable alternatives ; • Exclude the use of PFAS chemicals on their own, in formulations and in articles that are necessary for the MRO of existing products ; • Include a time-unlimited derogation for specific PFAS chemicals used fire suppression systems . We highlight that due to our sectors reliance on products from a wide range of industries (electronics, semiconductors, batteries etc.), our sector derogations for fluoropolymers would not be sufficient to protect our industry from widespread obsolescence of materials and processes and unpredictable side effects within the related industrial supply chains. We highlight that a blanket ban on fluoropolymers is a disproportionate risk management option given that the dossier submitters concern is on the conditions of use and risk management measures in place at their sites of manufacture and end-of-life, and not as such from their use. We note that although the dossier submitters group all PFAS chemicals into (1) PFAAs and PFAA precursors (2) Fluorinated gases and (3) Polymeric PFASs, the use tonnages for polymeric PFAS were ascribed to group 1 (see chapter 1.3.1 of the restriction report). In addition, we note that related to PFAS properties of concern given in Figure 4 of the restriction report, the only property relevant for fluoropolymers is “persistence”. There are more proportionate risk management options that would address the concern e.g. specific obligations under the Industrial Emissions Directive. Their potential for emissions at end-of life requires different considerations from non-polymeric PFAS as while they are “persistent” due to their extreme inertness; we understand that they are non-mobile, non-bioaccumulative and non-toxic\*. The potential for risk has not been demonstrated from this class of materials. Fluoropolymers have a unique combination of properties that make them ideally suited to applications with high performance requirements for safety and reliability for extended periods in harsh and extreme conditions of use. They are durable, stable and mechanically strong in harsh conditions, stable in air, water, sunlight, chemicals and microbes, chemically inert, non-wetting, non-stick, and highly resistant to temperature, fire and weather. There are no materials currently available that have this range of properties. A ban on their use will compromise existing safety standards in the aerospace sector and in other sectors (e.g. manufacturing, transport and storage of chemicals). With regards to fire suppression, we would like to point out that years of research to replace Halon to comply with the EU Ozone regulation deadline have demonstrated that PFAS are the only suitable Halon alternative, already implemented in some applications (cabin & cockpit portable and lavatory fire extinguisher systems) and in final stages of development for other (Cargo). The EU PFAS restriction as proposed would have devastating economic and operational consequences for aircraft OEMs and their customers associated with the regrettable substitution scenario. Considering the very high risk of not finding any other better alternatives to Halon 1211 & 1301 in due time, a time unlimited derogation is requested to allow current implemented halon replacement to be maintained and ongoing activities to continue with no disruption and uncertainties that the current proposal would generate.  We also note that the reporting requirements on manufacturers and importers of PFAS or PFAS containing articles as well as formulators of PFAS containing mixtures relying on derogations (paragraphs 7 & 8) did not consider the specificities of our sector. Due to both the complexity of our products and our global supply chains, it is not possible to collect, compile and report the information required under paragraph 7 within 18 months of the entry into force. The site specific management plans requirements given in paragraph 8 also cannot be implemented within 18 months of entry into force as the users will be need to collect information from all tiers of their supply chain and map PFAS in the 1000’s of parts, components, systems etc. that make up aerospace products. At least 5 to 10 years would be needed to be compliant with such requirements.  In addition, we highlight that the restriction refers to ppb levels in articles (paragraph 2) – the challenges associated with complying with the requirement were not considered by the dossier submitters as apriori to verify this, we would need to test all articles. This is not feasible for aerospace products as 1000’s of parts/components would need to be tested. In addition, standard test methods are not available for the range of articles that would need testing with this level of detection.  Please note the ASD response, which we strongly support, is also supported by the Space Restrictions Task Force (RTF), an initiative of the Materials and Processes Technology Board of the European Space Components Coordination (ESCC MPTB), which is a partnership of the European Space Agency (ESA), national space agencies, and space industry represented by ASD-Eurospace. In addition, ASD-Eurospace with the support of the RTF has prepared a complementary response to the present contribution focusing on equipment designed to be sent into space (ref. MPTB-ES-PO-0131), as they have not been considered as such in the current restriction proposal (“missing uses”).  \*see position paper from Fluoropolymers Product Group (FPG) available at https://fluoropolymers.plasticseurope.org/application/files/8716/7991/0281/21\_March\_FPG\_Statement\_on\_the\_PFAS\_REACH\_restriction\_report.pdf and submission #6148 in the public consultation |
| Answer to specific info request 1:  The aerospace sector uses were not included in Table 9 of the dossier and the list of uses given do not adequately include our uses and their specificities in terms of safety and reliability requirements. We ask that aerospace be included as a sector in its own right and its specific uses of PFAS chemicals be considered in the restriction dossier. Details of our sector wide uses are included in the ASD (Aerospace, Security and Defence Industries Association of Europe) reply to Q6. |
| Answer to specific info request 2:  See ASD (Aerospace, Security and Defence Industries Association of Europe) reply for Q6. |
| Answer to specific info request 3:  See ASD (Aerospace, Security and Defence Industries Association of Europe) reply for Q6. |
| Answer to specific info request 5:  See ASD (Aerospace, Security and Defence Industries Association of Europe) reply for Q6. |
| Answer to specific info request 6:  The dossier submitters did not consider the aerospace sector and the restriction proposal does not adequately address uses by this sector. Some aerospace uses would be covered under proposed/potential derogations. However, the scope and durations are inadequate. Many aerospace uses are not covered by a proposed or potential derogation. For this reason, we provide input of our sector wide uses together with information on the availability of alternatives and socio-economic impacts in the attachment provided in the ASD reply. The scale of the substitution requirement that would be imposed by the entry into force of this restriction, together with the specificities of our sector have not been considered by the dossier submitters. Their proposed RO2 does not include our sector and is therefore incomplete. We ask the dossier submitters to amend their proposal to include our sector and to take into account our considerations and requests as given in our general comments. |
| Answer to specific info request 7:  See ASD (Aerospace, Security and Defence Industries Association of Europe) reply for Q6 provided as attachments with a public part + a confidential annex (with case studies). |
| Answer to specific info request 8:  See ASD (Aerospace, Security and Defence Industries Association of Europe) reply for Q6. |

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| 8729 | Date:  2023/09/22 15:37  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Federation of Norwegian Industries  Org. country:  Norway  Attachment: | General Comments:  Please se attached document |
| Answer to specific info request 1:  please see attached document |

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| 8730 | Date:  2023/09/22 15:36  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Associazione produttori guarnizioni del Sebino  Org. country:  Italy  Attachment: | General Comments:  See attachment |
| Answer to specific info request 1:  See attachment |
| Answer to specific info request 2:  See attachment |
| Answer to specific info request 3:  See attachment |
| Answer to specific info request 4:  See attachment |
| Answer to specific info request 5:  See attachment |
| Answer to specific info request 6:  See attachment |
| Answer to specific info request 7:  See attachment |
| Answer to specific info request 8:  See attachment |

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| 8731 | Date:  2023/09/22 15:36  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Fertilizers Europe  Org. country:  Belgium  Attachment: | General Comments:  - |
| Answer to specific info request 1:  The fertilizer sector is not specifically mentioned within table 9 of annex XV, however several components/materials used in the equipment in place for the manufacture of fertilizing products may fall under categories included in Table 9. (See attached document with more information on application use of PFAS containing materials within the fertilizer sector) |
| Answer to specific info request 2:  Estimates for volumes applied in the sector as well as annual disposal of PFAS materials are included in the attached document. The produced fertilizing products do not contain added PFAS materials. |
| Answer to specific info request 5:  Please see the attached document with included estimates for PFAS quantities installed in the sector and on waste. |
| Answer to specific info request 6:  According to our knowledge there are no readily available alternative substitutes to replace the current PFAS containing materials used within fertilizer manufacturing and operations. Hence our request for a transition period of 10 years to develop suitable alternatives and phase out PFAS containing materials. |
| Answer to specific info request 8:  Information on uses of PFAS material in equipment installed in fertilizer manufacturing plants are detailed in the attached document, and on the socio-economic impact of an immediate ban. |

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| 8732 | Date:  2023/09/22 15:38  Content:  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Belgium  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  We consider that the document attached in this section, as well as the name of the company for which we are submitting these comments, should be treated as confidential (and as such, should not be disclosed), on the basis of two grounds: (i) the protection of the company’s commercial interests, pursuant to Article 4(2), first indent of Regulation (EC) No 1049/2001; and (ii) the protection of legal advice, pursuant to Article 4(2), second indent of Regulation (EC) No 1049/2001. First, the first indent of Article 4(2) of Regulation (EC) No 1049/2001 provides that “[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: commercial interests of a natural or legal person, including intellectual property […] unless there is an overriding public interest in disclosure”. In this respect, it should be noted that Regulation (EC) No 1049/2001 does not define the concept of commercial interests, except in so far as it specifies that such interests may cover the intellectual property of a particular natural or legal person. The EU Courts nevertheless stress that information withheld under the exception relating to the protection of commercial interests is information which is not generally known to persons belonging to the circles dealing with the type of information in question, within the meaning of that provision. The Court held that it is in principle appropriate for an EU institution to rely on general presumptions applying to certain categories of documents, similar general considerations being likely to apply to requests for disclosure of documents of the same nature (Joined Cases C‑39/05 P and C‑52/05 P, Sweden and Turco v Council, EU:C:2008:374, paragraph 50). In this respect, the General Court has for example confirmed that information on company methods and expertise, specific prices, details of budgets and timetables involved, and elements of business strategies were covered by a general presumption that their disclosure would in principle undermine the protection of commercial interests of the company and that the EU institution therefore did not have to put forward any concrete evidence to justify the non-disclosure of each document, in its entirety (Case T-651/21, Hans-Wilhelm Saure v Commission, EU:T:2022:526, paragraphs 106 and 107). In this case, the document attached in this section contains numerous business secrets and proprietary data of the company submitting it, that are not available in the public domain. It contains knowledge about the specific use of PFASs as refrigerants in medical devices. This expertise and this know-how are not publicly available and their disclosure would cause significant harm to the competitive position of the company, as it would undermine their commercial interests, including intellectual property. Moreover, the document contains and details numerical data as well as R&D work conducted by the company in respect to these particular uses. Knowledge of such information could allow third parties such as an applicant for access to document to access such information, that they could possibly use for their own benefit, which could ultimately undermine the commercial interests of the company submitting these comments. Moreover, there is no overriding public interest in the present case that would impose the disclosure of the name of the client. According to the case-law of the EU Courts (see, for example, Case C-127/13, Strack v Commission, EU:C:2014:455, paragraph 128), the burden falls on the applicant for access to documents, first, to demonstrate the existence of a public interest likely to prevail over the reasons justifying the refusal of the documents concerned and, second, to demonstrate precisely in what way disclosure of the documents would contribute to assuring protection of that public interest to the extent that the principle of transparency takes precedence over the protection of the interests which motivated the absence of disclosure (Case T-634/17, Anikó Pint v European Commission, EU:T:2018:662, paragraph 48). As such, it is only where the particular circumstances of the case substantiate a finding that the principle of transparency is especially pressing that that principle can constitute an overriding public interest capable of prevailing over the need for protection of the information (Joined Cases C-514/07 P, C-528/07 P and C-532/07 P, Sweden and Others v API and Commission, EU:C:2010:541, paragraphs 156 to 159). In this case, there is no such overriding public interest nor has one been claimed. Second, the second indent of Article 4(2) of Regulation (EC) No 1049/2001 provides that “[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: […] legal advice […] unless there is an overriding public interest in disclosure”. In respect of that exception, as highlighted by the EU Courts (see, for example, Joined Cases C 39/05 P and C 52/05 P, Sweden and Turco v Council, EU:C:2008:374, paragraph 37), the examination to be undertaken by the institution concerned when it is asked to disclose a document must necessarily be carried out in three stages. First, it must satisfy itself that the document which it is asked to disclose indeed relates to legal advice and, if so, it must decide which parts of it are actually concerned and may, therefore, be covered by that exception. Secondly, it must examine whether disclosure of the parts of the document in question which have been identified as relating to legal advice, would undermine the protection of that advice. Thirdly, if it takes the view that disclosure of a document would undermine the protection of legal advice, it should ascertain whether there is any overriding public interest nevertheless justifying disclosure (See Case C-408/21 P, Council v Pech, EU:C:2023:461, paragraphs 37 to 39). In the present case, we submit that the identity of the client (client-attorney relationships are privileged under ethical rules) as well as the content of the document should be considered confidential under the protection of legal advice. It is, firstly, undisputed that the document constitutes legal advice as it is submitted by the law firm relating to their engagement by their client to advise them in submitting comments in the context of the public consultation on the PFAS Restriction Proposal. Secondly, the law firm’s identity being linked to the present comments in a public manner, disclosing the name of their client would lead to the disclosure of the privileged and confidential nature of the client’s relation with its attorneys. Thirdly, as demonstrated above concerning the protection of commercial interests, there is no overriding public interest in the present case that would impose the disclosure of the confidential information. The name of the company on whose behalf these comments are submitted as well as the document attached in Section V should as such be entirely confidential and their disclosure prevented, in application of the exceptions to disclosure contained in Article 4(2), first and second indents of Regulation (EC) No 1049/2001. | General Comments:  Please see confidential attachment in Section V. |
| Answer to specific info request 1:  Please see confidential attachment in Section V. |
| Answer to specific info request 2:  Please see confidential attachment in Section V. |
| Answer to specific info request 5:  Please see confidential attachment in Section V. |
| Answer to specific info request 6:  Please see confidential attachment in Section V. |
| Answer to specific info request 8:  Please see confidential attachment in Section V. |

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| 8733 | Date:  2023/09/22 15:39  Content:  Environmental emissions  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CLP-HPG Dutch Association of Pump Manufacturers and Suppliers  Org. country:  Netherlands  Attachment: | General Comments:  See the attachement |
| Answer to specific info request 1:  See the footnote in the attachement |

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| 8734 | Date:  2023/09/22 15:38  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  KARL MAYER STOLL Textilmaschinenfabrik GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  The confidential attachment contains detailed information about fluoropolymer coated functional components that are used in our machines. It also contains knowhow which we deliver for your information but which should not made public to protect our commercial interests | General Comments:  Karl Mayer Stoll Textilmaschinenfabrik GmbH is a European based textile machinery manufacturer with various focus areas and subsidiaries, all of which support the global textile-producing industry with machinery and services. Through particularly innovative, sustainable and high-quality products, we have succeeded in achieving world market leadership for various products. We are using fluoropolymers in several machines as industrial nonstic coatings. Main use is a nonstic coating on drying cylinders. For our usecase the properties of long-chain Fluoropolymers are essential for design and function in our B-to-B-applications.  request of exception: the respondend requests an exception for the use of PFTE, FEP and PFA fluoropolymers for the use of our specific need. for more details pls follow our answers of specific questions as well as our confidential attachment V |
| Answer to specific info request 1:  Our use of Fluoropolymers is not mentioned in Table 9. We are using fluoropolymers in several machines as industrial nonstic coatings. Main use is a nonstic coating on drying cylinders. |
| Answer to specific info request 2:  The respondent is aware that the coating process using fluoropolymers PTFE, PFA or FEP in liquid or powder form must be carried out very responsibly. We therefore do not carry out our own coatings, but have qualified leading European suppliers for this purpose, whose core business is precisely such coatings and who have the highest level of expertise. During the use of the coated drying cylinders it is ensured that the conditions always stay within the coating intended use. Since we place high safety demands on our machines, the temperatures that can actually be set for these products are significantly below the permitted upper limit. We are therefore not aware of any emissions when operating our drying cylinders. As our cylinders still have a high value for steel recycling with end of life our customers will provide the cylinders to a steel mill for recycling. With entering this circular recycling stream all coatings will be incinerated into HF without spreading out. |
| Answer to specific info request 3:  The available data and related analysis to end-of-life-stage are reported in the Confidential Attachment- Section V |
| Answer to specific info request 5:  Data on used metric tons of polymeric PFAS are given in the Condidential Attachement V |
| Answer to specific info request 6:  6a FEP, PFA and PTFE to be used as nonstic coating on drying cylinders to be used in textile and nonwoven industry. Speaking about the annual tonnage and emissions the respondent has given figures of his own product portfolio in the confident Attachement V. 6b Key functionalities of these kind of flouropolymers is the very low surface energy, high cleanability and in a result a no stick property in combination with high corrosion resistance as well in combination with the relevant temperature resistancy. During last decades we went into deep search not only to optimize the recipe being used by us but also to look for alternative solutions – like for example used in frypans nowadays. But simply said: alternatives, which can offer same basket of combined performance do not exist! It is hard to conceive that new materials can affordably and economically be available on the market within terms of a time limited derogation for the need of our complex coating application. As we do not see a realistic scenario for a substitution for the coating we use for above mentioned coating application the socio-economic impact will be huge for European textile machine manufacturers as well as for textile producers. For more details pls see confident Attachement V |
| Answer to specific info request 7:  Concluding all above considerations the respondent would like to make ECHA as well as European regulators aware multiple serious impacts not only on the respondent itself but moreover also for the European textile manufacturing - for more details pls see confident Attachement V Based on that we are respectfully asking ECHA as well as all regulators for a major reconsideration of the Annex XV restriction report in order to exempt from any restriction thermoplastic polymeric PFAS used in above-described application. Involved are FEP, PFA and PTFE. We strongly are convinced that any time-limited derogation would not help out . The respondent´s policy has aways been to act in a very responsible way and particularly whenever human and/or environmental health are to be taken into consideration. Therefore we are committed to do our own part to establish a way to better monitor and control end of life of coated items, so to establish fair and economically sustainable rules to be adopted by the downstream Industries. |
| Answer to specific info request 8:  Information on the non listed (Annex XV restriction proposal) use of polymeric PFAS in our specific industrial B-To-B-Coating application have been already given in previous sections |

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| 8735 | Date:  2023/09/22 15:43  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  Belgium  Company name confidential:  Yes | General Comments:  REINTJES Benelux BV appreciates the opportunity to provide the following comments in response to the proposal of this PFAS restriction. REINTJES supports the EU's efforts to protect human health and environment. However, this proposal does not seem to adequately address the impact on a wide range of industries. For this reason, we comment on this proposal as follows. A blanket restriction of the entire PFAS substance group without a differentiated, substance- and application-specific risk assessment and solely due to the persistence of some PFAS is not appropriate. In order to ultimately achieve a sustainable overall balance of resource conservation and environmental impact, a restriction is only justified in cases where the risks to humans and the environment cannot be controlled. It should be taken into account that the PFAS definition includes substances with different properties and that neither all PFAS are equally persistent. This puts almost risk-free chemicals on an equal footing with substances of very high concern with properties that require regulation. As part of a differentiated approach, it is urgent to ensure that only those substances whose use poses an unacceptable risk to the environment or human health are banned. Otherwise, there is a risk that chemicals that play a crucial role in innovative technologies will be driven out of the market. For example, manufacturers of hydraulic components such as pumps, motors, valves and cylinders as well as manufacturers of valves and compressors are affected. PFAS, mostly fluorinated polymers, are often used in seals, hoses, pipes, valves and coatings that we absolutely need for our products. While in some cases "only" the performance of some products would be massively affected, some products could no longer be manufactured, which would mean a very high impact on not only our company, our customers and our market but the entire shipping industry. |
| Answer to specific info request 1:  - Electronics and semiconductor (Annex E.2.11.) - Construction products (Annex E.2.13.) - Lubricants (Annex E.2.14.) - Transport (Annex E.2.10.) |

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| 8736 | Date:  2023/09/22 15:42  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  TransnetBW  Org. country:  Germany | General Comments:  - |
| Answer to specific info request 1:  TULAC (Annex E.2.2.) • Professional apparel (including PPE): Personal protective equipment intended to protect users against e.g., substances and mixtures which are hazardous to health, electric shock and live working • Other: Textiles for use in engine bays in automotives (for noise and vibration insulation) Application of fluorinated gases (Annex E.2.8.) • Insulating gas in electrical equipment Electronics and semiconductor (Annex E.2.11.) • Electronics • Semiconductors Energy sector (Annex E.2.12.) • Sector as a whole • Additional derogation for polymers and additives in liquids are proposed section 2.6 and 2.7, respectively. Constructional products (Annex E.2.13) • Architectural coatings and paints • Coil coatings • PTFE thread sealing tape • Side-chain fluorinated polymers used for surface protection/ sealants • Fluorosurfactants as wetting/ levelling agents in e.g. coating, paints and adhesives Lubricants (Annex E.2.14.) • Sector as a whole |
| Answer to specific info request 2:  As users, transmission system operators (TSOs) currently do not have a comprehensive overview of the use of PFASs in components of their electrical equipment. Moreover, TSOs also lack the data to determine the amount of PFAS contained in their equipment, as well as the PFAS used to manufacture and disassemble this equipment. However, an estimation of emissions during the use phase can be provided: • No emissions of solid materials • Possible emissions of fluids and lubricants. The exact amount of emission is unknown but presumably very low. • Possible emissions of fluorinated gases: The average emission rate for high voltage electrical equipment is below 0.5 % per year. High voltage equipment consists of a wide variety of materials. The ratio differs significantly with respect to the considered asset. As an example the share of PFAS containing commodities of 420 kV gas insulated switchgears (GIS) in standard configuration is given: • synthetic materials approx. 6% • insulating gas approx. 5% TSOs authorize waste management contractors for disposal of synthetic materials, such as PMMA and PTFE and insulating gases according to local regulations |
| Answer to specific info request 6:  Table A.1 of Annex A indicates PFAS applications regarding the “Energy sector” as researched in detail. However, the assets operating in the electric power transmission grid are not addressed in the Annex XV, nor in Annex A of Annex XV. Hence, an analysis of alternatives and socio-economic analysis can not be provided. Subdivision of the energy sector as given in chapter 2.8 is urgently needed. |
| Answer to specific info request 7:  The use cases given in Table 8 in Annex XV does not address assets operating in the electric power transmission grid. Derogations for the energy sector as given in chapter 2.8 are urgently needed. |
| Answer to specific info request 8:  TSOs build and operate the critical power grid infrastructure to supply electricity to European industry and citizens. TSOs make sure to keep the environmental impact of the grid to a minimum and even enhance nature restoration and biodiversity in their corridors. The sophisticated high and extra high voltage equipment used in power grids is built to last 40+ years. It is designed to operate and withstand extraordinary and harsh conditions, such as high pressure, extreme voltage levels and temperatures, and to guarantee the functioning and resilience of the grid at any time. The use of PFAS in solid, liquid, and gaseous components of grid equipment is determined by manufacturers to ensure the needed requirements for its performance and reliability. The sophisticated high and extra high voltage equipment used in power grids is built to last 40+ years. It is designed to operate and withstand extraordinary and harsh conditions, such as high pressure, extreme voltage levels and temperatures, and to guarantee the functioning and resilience of the grid at any time. The use of PFAS in solid, liquid, and gaseous components of grid equipment is determined by manufacturers to ensure the highest requirements for its performance and reliability. A restriction that does not take into account network-specific use cases could lead to the unavailability of critical assets and, thus, to unpredictable effects with regard to system security. Due to a lack of data, TSOs do not yet have a comprehensive overview of the use of PFAS in the components of their electrical equipment, nor the PFAS used to manufacture this equipment. Furthermore, there is also insufficient information on possible alternatives to replace them. European TSOs are committed to protecting the public and workforce wherever risks stemming from PFAS are identified. Therefore, typical use cases for PFAS where information exists are highlighted and the need for use case-specific derogations in the restriction proposal in case no alternatives are available is stressed. 1. Inherent dilemmas and trade-offs between environmental concerns of PFAS and climate objectives High-voltage equipment using PFAS gases is typically installed in critical network nodes. Their shutdowns would cause the rejection of renewably generated power. This would equal a tremendous amount of wasted resources. The proposal to restrict PFAS should not prevent either the decarbonisation of the electricity grid infrastructure or the grid development, which is essential to properly deliver the energy transition (by allowing the integration of renewable energies and the electrification of uses). The PFAS currently used for the electricity grid infrastructure contributes to its functionality and high efficiency. Complete restrictions of their placing on the market and use should always be considered in light of the availability of alternatives. Decarbonisation and the protection of human health and the environment are key. ECHA's proposal to restrict PFASs should, therefore, strike for a good balance between both objectives. 2. PFAS in solid components and spare parts of electrical equipment 2a. Solid components PFASs are used in electrical grid equipment, machinery components and parts, such as insulated nozzles, sealings, plain bearings, gaskets etc. The insulated nozzle is a key component for interrupting fault current (the arc of a short circuit current) inside a circuit breaker. More use cases are further specified in the annex. Once manufactured, solid components with PFAS are usually installed within the machinery. The decommissioning and recycling are carried out respecting all applicable legislation and in close collaboration with manufacturers. TSOs are not aware of any alternative solutions to the PFAS use cases listed in the Annex of this document. Therefore, an undifferentiated restriction of PFAS for these components of grid equipment would signify a ban on new equipment and spare parts for critical infrastructure within 18 months after its entry into force. This would effectively bring all current European grid development projects to a halt and then would endanger the ongoing energy transition, as no manufacturer is currently able to supply PFAS-free equipment. As research and development of alternatives is only starting, it is urgently needed that ECHA acknowledges this gap in the current proposal and adds a derogation of 13,5 years for solid components in electrical transmission equipment. More specifically, derogation 6. in the restriction proposal for fluoropolymers and perfluoropolyethers should be extended for use in high-voltage electricity transmission equipment by adding the paragraph “6 g high-voltage electricity transmission equipment”. 2b. Spare parts containing PFAS should be exempted Many PFAS are used in existing electric equipment already installed with a minimum lifetime of 40 years. It is, therefore, necessary that the supply of spare parts is secured throughout this lifetime. The operation, maintenance, repair and extension of existing equipment containing PFAS must be ensured until the end of its lifetime, as PFAS-free spare parts may not work in the originally designed equipment. Otherwise, they would need to be decommissioned prematurely, entailing additional environmental and climate-related burdens, without consideration of circular economy or reparability principles. TSOs reiterate and stress the importance of being able to use equipment during its lifetime. Therefore, TSOs recommend an unlimited derogation for using spare parts containing PFAS in existing electrical equipment. 3. PFAS in liquids and lubricants Several liquids and lubricants used for the servicing and maintenance of electrical equipment use PFAS. The properties of mineral oils and lubricants are modified with PFAS additives to fulfil the needed quality demands, e.g., on temperature behaviour and ageing stability. They are used, for instance, in circuit breakers, which need to work impeccably when used. TSOs are not aware of any alternative solutions to the use cases listed. An undifferentiated restriction of lubricants and liquids containing PFAS would impede TSOs from carrying out their legal obligation to maintain and service their equipment to ensure proper functionality and efficient operation of the grid, bearing considerable risks regarding grid stability, security of supply and workers’ safety. Therefore, the proposal to allow a 13,5-year derogation for lubricants used under harsh conditions is strongly supported. On top of that, TSOs recommend a 13,5-year derogation for PFAS in liquids, in particular technical mineral oil with PFAS additives, until alternatives have been developed and proven to satisfy comparable quality standards regarding long-term reliability and performance requirements. 4. PFAS in gases 4a. Gases for operation, maintenance and extension containing PFAS should be exempted In recent years, TSOs have been using PFAS-containing gases as insulation medium in electrical switchgear to replace SF6, the most potent greenhouse gas, and decarbonise their electric equipment. For the new installations above 145 kV, as well as for specific uses on all voltage levels, TSOs currently have limited possibilities to replace SF6. One key component to do so has been PFAS-containing insulation gases, such as fluoronitrile (C4F7N). The application of the gases in electrical equipment, listed in the annex per use-case, is used in closed cycles and has state-of-the-art leakage detection devices to ensure smooth operation, protect the environment and minimise workforce exposure. As of today, it is not certain whether PFAS-Gas-free solutions above 145kV and for specific uses on all voltage levels will be commercially available in 6,5 years time, also in sufficient quantity for all ranges of TSOs application. This is due to long development, qualification, and standardisation processes. If PFAS in switchgear insulation gases were banned after the derogation period of 6,5 years, it would mean the already ordered and installed equipment supposed to operate with PFAS gases may not be put into operation, maintained, nor extended after the ban date and that existing equipment would have to be put out of order and become a stranded asset. It must also be ensured that switchgear operating with PFAS gases that have been lawfully put into operation according to the F-Gases Regulation can be refilled for maintenance purposes or extended with the corresponding gas as long as it cannot be maintained or extended with PFAS-free gases. Therefore, TSOs recommend an unlimited derogation for PFAS gases used for refilling, maintenance, or extension purposes of switchgear. Replacing existing switchgear operating with PFAS gases before their end-of-life would lead to stranded assets, which would contradict the principles of reparability and circularity. 4b. Derogation of PFAS-containing gases will help speeding up the PFAS-free developments The present draft of F-Gases Regulation forces TSOs to install fluornitril based assets until alternative solutions are available. TSOs believe that derogation of the PFAS Gases within 6,5 years, as proposed by ECHA, would strengthen the developments of the alternative PFAS-free solutions and hence the installations of PFAS-Solutions would be limited to minimum. Thus, TSOs urge ECHA and policymakers to take into account the ongoing negotiations on the draft F-Gases Regulation. 5. Resulting additional derogation proposals Based on the explanations above, the following derogation propsals should be taken into consideration in the “ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)” in the table “Proposed restriction - Annex XVII entry PFASs (Restriction Option 2)” beginning at the page 4 of the report: • add “4.d. spare parts necessary for operation, maintenance, repair and extension in energy sector.” • add “5.u. Additives in mineral oils and lubricants in high-voltage electricity transmission equipment until 13.5 years after EiF” add “6.g. Fluoropolymer applications in high-voltage electricity transmission equipment until 13.5 years after EiF” Annex: Non-comprehensive overview of the of PFAS in components of TSO equipment Disclaimer: As users, TSOs currently do not have a comprehensive overview of the use of PFASs in components of their electrical equipment. Moreover, TSOs also lack the data to determine the amount of PFAS contained in their equipment, as well as the PFAS used to manufacture this equipment. The following overview shows typical use cases for PFAS for which information is available for the TSOs. a) Solid Asset / equipment: Gas insulated switchgear (GIS) Transformer / shunt reactor Circuit breaker Instrument transformer HV-Cable Converter Capacitor Bank Offshore Systems Interconnectors Reactive-power compensation systems Measurement sensors Grid protection Network control Communication Power electronics (HVDC Converters, STATCOM) Usage: Electrical Insulation • Wires of coils • Contact systems Electronics • Printed Circuit Boards • Cable insulation • Electronic components Gaskets Thermally stable and insulating pipes Mechanical components • Drives • Actuators • Insulated nozzles PFAS (incomplete): PTFE PVDF b) Liquide Asset/equipment: Transformer / shunt Reactor Instrument transformer Converter Capacitor bank Offshore systems Interconnectors Reactive-power compensation systems Usage: Electrical insulation Lubricants Corrosion protection painting Thermally stable paintings PFAS (incomplete): Additives (e.g. PFPE) c) Gaseous Asset/equipment: Electrical insulation Instrument Transformer Offshore systems Interconnectors Reactive-power compensation systems PFAS (incomplete): Fluorinated gas (C4-FN) |

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| 8737 | Date:  2023/09/22 15:43  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment: | General Comments:  SEE ATTACHMENT |
| Answer to specific info request 1:  SEE ATTACHMENT |
| Answer to specific info request 2:  SEE ATTACHMENT |
| Answer to specific info request 3:  SEE ATTACHMENT |
| Answer to specific info request 4:  SEE ATTACHMENT |
| Answer to specific info request 5:  SEE ATTACHMENT |
| Answer to specific info request 6:  SEE ATTACHMENT |
| Answer to specific info request 7:  SEE ATTACHMENT |
| Answer to specific info request 8:  SEE ATTACHMENT |

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| 8738 | Date:  2023/09/22 15:43  Content:  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Unsere Maschinen und Anlagen für Jahrzehnte gebaut werden. Vor diesem Hintergrund ist es wichtig, dass Ersatz- und Gebrauchtteile in dem Beschränkungsvorschlag berücksichtigt werden. Weder grundsätzliche Ausnahmen von der Regelung, noch längere Übergangsfristen sind vorgesehen. Das bedeutet, dass nach der Übergangsfrist von 18 Monaten Reparaturen, respektive der regelmäßige Austausch von Verschleißteilen in langlebigen Produkten, wie z.B. der Austausch von Dichtungen oder Schläuchen in Industrieanlagen, nicht mehr möglich wären. Selbst dort, wo es Ausnahmen gibt, sind diese für nur fünf und zwölf Jahre vorgeschlagen. Es ist nicht klar, ob und wie eine Verlängerung der bestehenden Ausnahmen beantragt werden kann. Aufgrund fehlender standardisierter, einfacher Analysemethoden lässt sich nicht kontrollieren, wie die Umsetzung des Beschränkungsvorschlags, z.B. insbesondere hinsichtlich importierter PFAS-haltiger Produkte, zukünftig von der Marktüberwachung sichergestellt werden kann. Das würde dazu führen, dass PFAS-haltige Erzeugnisse in der EU zwar nicht mehr hergestellt werden könnten, diese jedoch eventuell weiter den Weg in die EU finden würden. Ein unkontrollierter Import PFAS-haltiger Produkte würde zu erheblichen Wettbewerbsnachteilen führen. |
| Answer to specific info request 3:  Wir sind ein mittelständisches und familiengeführtes Unternehmen im Maschinenbau. Die Produkte werden gewerblich genutzt und werden nicht in einen öffentlichen Kreislauf entsorgt. Eine hohe Menge von PFAS-Anteilen ist bei den Subkomponenten nicht zu erwarten, somit wird kein erkennbarer Einfluss der Emissionen erwartet. Die Lebensphasen von bis zu 25 Jahren sind sehr lang. Die Stückzahl der Maschinen (Gesamtprodukt) ist max. 4000 bis 5000 Stück pro Jahr. Durch den hohen Preis von Fluorpolymeren wird deren Einsatz in unseren Produkten (einfach + kostengünstig) deshalb in den Maßen nicht Bestandteil sein. Das Potential zur Verunreinigung von Grundwasser, Oberflächengewässer und Böden durch potentiell sehr geringen Mengen an PFAS in vereinzelten Subkomponenten in Maschinen wird als sehr niedrig bis nicht relevant im Verhältnis zu anderen möglichen PFAS-Emissionen eingeschätzt. Deshalb sind pauschale Beschränkungen für uns als Maschinenbau-Unternehmen nicht sinnvoll. Auch deswegen ist es notwendig, Anwendungen im Konsumbereich (B2C) von denjenigen im B2B-Bereich zu unterscheiden. Industrielle Unternehmen können durch ein professionelles Risikomanagement dafür Sorge tragen, dass mit PFAS, PFAS-haltigen Materialien und Produkten über den gesamten Lebenszyklus hinweg fachgerecht umgegangen wird. |
| Answer to specific info request 4:  Durch aktuell nicht bekannte Anteile im Gesamtprodukt (Maschine) von PFAS, wird deshalb auch für die Reycling-Industrie eine Bewertungsgrundlage nicht vorhanden sein. Materialströme können kaum getrennt werden. Und gerade deshalb ist eine Trennung von Industriezweigen oder Ausnahmen für Industriezweige (bzw. Produktarten) wichtig. Produkte und Komponenten (Erzeugnisse) im Konsumbereich (B2C) sollten von denjenigen im B2B-Bereich klar unterschieden und nicht gleich behandelt werden. So wäre wie bei anderen Material- bzw. Entsorgungsgesetzgebungen eine Trennung in den Wert- und Recycling strömen realisierbar. |
| Answer to specific info request 6:  Gewerbliche Reinigungsmaschinen, sind nicht beachtet worden. Trotzdass gewerbliche Reinigungsmaschinen ein Nennwertes Markt in Deutschland und Europa sind. 2018 lag der Umsatz der Branche in Deutschland bei rund 940 Millionen Euro. Von der Lieferfähigkeit der Branche ist für die deutschen und europäischen Gebäudereinigerbranche elementar. Die Gebäudereinigung ist das beschäftigungsstärkste Handwerk Deutschlands. Aktuell sind rund 650.000 Personen in der Branche beschäftigt. 1. Lieferversorgung gefährdet, da Kernkomponenten betroffen sind: Für die Hartbodenreinigung werden mit zwei wesentlichen Medien verwendet, nämlich mit Wasser und Luft. Die Funktion wird mit vielerlei Komponenten sichergestellt - speziell durch Schläuche, Dichtungen und Ventilen. Durch die Vielzahl an Komponenten und breite Lieferversorgung, größtenteils innerhalb der EU und Deutschland, ist in Kombination mit unserer mittelständischen Struktur gehen wir davon aus, dass relevante Komponenten vom Markt verschwinden. Somit ist von Produktionsstopps, über Produktabkündigungen bis hin zur Betriebsaufgabe auszugehen. Aus unserer Sicht ist somit eine unternehmerische Planungsgrundlage nicht mehr gegeben. Durch die Vielzahl an Komponenten (bis zu 100 Teile pro Maschine) und Lieferanten (ca. 400) 2. Beeinflussung aktuell befindlichen Maschinen: Durch die Maschinenpopulation, die sich im Markt befindet wird ein wesentlicher Teil des Umsatzes mit Ersatzeilen, Zubehör und Reparaturen erzielt. Wenn wesentliche Komponenten als Ersatzteil entfallen können reparaturfähige in jeder Ihrer Lebensphasen nicht mehr Instandgesetzt werden. Hier besteht also die Gefahr, dass ein enormer finanzieller Schaden für das Handwerk sowie auch ökologisch entsteht. Für das Inverkehrbringen von Ersatz-, Verschleiß- und Gebrauchtteilen sind zum Zwecke der Nachhaltigkeit und Wirtschaftlichkeit Ausnahmen von der Beschränkung erforderlich (Repair as produced-Prinzip). Diese sind unbefristet oder zumindest über einen wesentlich längeren Zeitraum, als die derzeit vorgesehenen Übergangsfristen, zu gewähren. Bei Anwendungen mit extremen Rahmenbedingungen gibt es oft keine geeigneten Alternativen zu PFAS-haltigen Produkten. Der Einsatz von PFAS in industriellen Anwendungen (z.B. Dichtungen, Schläuchen, Leitungen, Ventilen, Kompressoren und Beschichtungen) trägt unter anderem zur Sicherheit, Ressourceneffizienz und Langlebigkeit industrieller Anlagen bei. |
| Answer to specific info request 7:  Die im Beschränkungsvorschlag vorgesehene 18-monatige Übergangsfrist ist zu kurz für industrielle Anwendungen. Schon um die möglichen Alternativen auf Funktionalität und sichere Anwendung zu prüfen, für den Serieneinsatz zu qualifizieren und vielfach im Rahmen von EU-Gesetzen zuzulassen, wird ein Zeitraum von mehreren Jahren benötigt. Somit muss auch die generelle Übergangsfrist mehrere Jahre betragen. |

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| 8739 | Date:  2023/09/22 15:44  Content:  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |

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| 8740 | Date:  2023/09/22 15:44  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  to protect the commercial interests of the company including intellectual property | General Comments:  Der Maschinen – und Anlagenbau stellt sehr spezifische, auf die Anforderungen von verschiedenen Industriezweigen wie Automobilindustrie, Medizintechnik, Luft- und Raumfahrttechnik, Präzisionsmaschinen, Energietechnik und Halbeiterfertigung ausgerichtete, Maschinen und Anlagen her. Viele Unternehmen des Maschinen- und Anlagenbaus sind mittelständisch. Die Innovationskraft und Wirtschaftsleistung gerader dieser Unternehmen ist sehr groß. Auch für den Arbeitsmarkt haben mittelständische Unternehmen des Maschinen- und Anlagenbaus eine große Bedeutung. In Maschinen und Anlagen für Fertigungsprozesse sind polymere PFAS aktuell in vielen Anwendungen nicht ersetzbar, weil diese außergewöhnliche Eigenschaften wie hohe chemische und/oder thermische Beständigkeit bei hoher Schlagzähigkeit und sehr geringer Oberflächenspannung aufweisen. In manchen Anwendungen ermöglichen sehr kleine Bauteile aus polymeren PFAS, die in geringen Stückzahlen verbaut sind, erst den Betrieb der Maschine oder Anlage und damit einen relevanten Produktionsprozess in den oben genannten Industriezweigen. Aus diesem Grund wird eine Ausnahmeregelung für den Einsatz von polymeren PFAS in Anlagen und Maschinen beantragt. |
| Answer to specific info request 1:  See confidential attachment in Section V |
| Answer to specific info request 2:  See confidential attachment in Section V |
| Answer to specific info request 3:  See confidential attachment in Section 5 |
| Answer to specific info request 5:  See confidential attachment in Section V |
| Answer to specific info request 6:  See confidential attachment in Section V |
| Answer to specific info request 7:  See confidential attachment in Section V |
| Answer to specific info request 8:  See confidential attachment in Section 5 |

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| 8741 | Date:  2023/09/22 15:45  Content:  Environmental emissions  Baseline  Description of analytical methods  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Product name Ion-exchange resins and synthetic adsorbent This comment is not about the scope of the restriction but wants point out a remedy for the locally high level of PFAS in drinking water. Since 2014 several anionic an non ionic exchange resins were sucessfully tested for their capacaties of removing PFAS, especially PFOA and PFOS from water.  We would like to recommend these publications: Chemosphere, Volume 272, June 2021, 129777 PFAS removal by ion exchange resins: A review Fuhar Dixit, Rahul Dutta, Benoit Barbeau, Pierre Berube, Madjid Mohseni https://doi.org/10.1016/j.chemosphere.2021.129777  Research Paper: Chemosphere, Volume 341, November 2023, 139983. “Important properties of anion exchange resins for efficient removal of PFOS and PFOA from groundwater” Shahanaz Parvin, Hiroe Hara-Yamamura, Yuma Kanai, Aki Yamasaki, Tadashi Adachi, Sovannlaksmy Sorn, Ryo Honda, Hiroshi Yamamura https://doi.org/10.1016/j.chemosphere.2023.139983 The second one is reported from Japanese researchers, and some results of DIAION products are included. One of the products with the largest capacity for the widest range of PFAS is this highly porous material. (Effectiveness to PFOS (99.9%) https://www.diaion.com/en/products/ion\_exchange\_resins/strongly\_basic\_anion/data\_sheet\_hpa/pdf/hpa25m.pdf With its properties to accumulte PFAS it can support the analytics of low contaminated aquaous samples. |
| Answer to specific info request 1:  Drinking water treatment, Industrial food and feed production |
| Answer to specific info request 2:  During its service life the product will collect PFAS, at the end of the lifetime, the product can easily be collected and regenerated or incinerated. |
| Answer to specific info request 3:  There will be no emmissons. |
| Answer to specific info request 4:  No impacts. |
| Answer to specific info request 10:  With its properties to accumulate PFAS it can support the analytics of low contaminated aquaous samples. |

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| 8742 | Date:  2023/09/22 15:47  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Aspen Oss B.V.  Org. country:  Netherlands  Attachment:  <redacted>  Privacy statement:  Protection of commercial interests | General Comments:  Based on the information presented we propose a derogation for the use of fluoropolymers in the manufacturing of active pharmaceutic ingredients. Taking into consideration the manufacturing of APIs is specifically regulated in the EU with extensive evaluations and approval processes by designated bodies with specific expertise and experience. Including the use of PFASs in a highly controlled manufacturing environment. Whereas it should also be noted a restriction on the use of fluoropolymers would have a negative impact on the availability and security of supply of medicines and their future alternatives. |
| Answer to specific info request 3:  Enclosed in the confidential attachement |
| Answer to specific info request 6:  Enclosed in the confidential attachement |

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| 8744 | Date:  2023/09/22 15:49  Content:  Scope or restriction option analysis  Information on alternatives  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Linde plc  Org. country:  Ireland  Attachment: | General Comments:  Linde welcomes the opportunity to provide comments and feedback to the proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs) as set out in the “Annex XV restriction report” of March 22, 2023. This comment relates to Linde’s industrial and medical gases business. Please note that separate comments have been submitted also from our coating technology and hydrogen fuelling business entities (cf. submissions from “Praxair srl” and “Linde Hydrogen Fueltech GmbH”). In this context, Linde would also like to draw attention to the separate statements submitted by our European sector association, the European Industrial Gases Association (EIGA), as well as various national sector associations, including the British Compressed Gases Association (BCGA), which we also endorse. Linde supports the overall intent of the restriction proposal in reducing emissions of PFAS and their degradation products into the environment and that certain exemptions have been proposed by the report. However, not all safety critical uses of Polymeric PFAS components and materials have been adequately considered. Linde therefore requests maximum derogations for use of Polymeric PFAS in the industrial and medical gases industry, in particular for harsh and extreme conditions in manufacture, handling, transport, and use, with the opportunity for further review if safe alternatives don’t become available and proven to meet all requirements in that time. Moreover, Linde also provides information related to the proposed derogation to allow further time to replace existing refrigeration units containing Fluorinated Gases with alternative refrigerants. Further information and details on specific uses of Polymeric PFAS in the industrial gases industry, emissions during use and end of life as well as about the use of fluorinated gases in existing refrigeration equipment can be found on the attached document. |
| Answer to specific info request 1:  This comment is related to the sector of Industrial and medical Gases and sub uses of sealing compounds, lubricants, rotating parts, flexible hoses. These sectors and sub-uses were not specifically listed in the Annex XV report The Sector Applications of fluorinated gases with Sub-use refrigeration is also covered in this comment |
| Answer to specific info request 2:  See also non confidential attachment Sector Applications of fluorinated gases with Sub-use refrigeration – Emissions during manufacture – not within our control Emissions during use – kept to a minimum as leaks will be monitored, reported and repaired due to F-GAS regulations Emissions during end of life – kept to a minimum as product is recovered and recycled due to F-GAS regulations Industrial and medical Gases uses of fluoropolymers for sealing compounds, lubricants, rotating parts, flexible hoses Emissions during manufacture – not within our control Emissions during use – minimal as components are chosen for their high durability in use and that they are primarily used directly within the gas technical and chemical process area with hermetic sealing, meaning without contact with the atmosphere. Emissions during end of life – As a responsible Industry user committed to sustainability and minimizing our own environmental resource intensity, we would welcome the opportunity to work with local partners and regulators to ensure continuous improvement and compliance in end-of-life waste management. |
| Answer to specific info request 5:  The use of fluorinated gases in existing refrigeration equipment is proposed for a 12 year derogation. Leaks and emissions of refrigerant gases in use are kept to a minimum due to strict leak monitoring requirements of F-Gas regulations and the need to control Greenhouse gas emissions. See attachment for further information. |
| Answer to specific info request 6:  Please see attached document explaining the uses of Polymeric PFAS in the Industrial and Medical Gases industry and downstream customers, the lack of feasible replacements and potential consequences of inferior components. At this stage alternatives are not technically feasible due to the harsh conditions and chemical compatibility that the chemicals need to withstand. |

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| 8745 | Date:  2023/09/22 15:54  Content:  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Information submitted in the Confidential Attachment shows commercial numbers, e.g. tonnage of used PFAS, which allow conclusions on the size of the business. Also, it contains sensitive internal information on know-how and status of R&D activities which should be protected from restricted for public sharing. | General Comments:  The following input concerns hydrogen related applications, namely PEM (proton exchange membrane) electrolysis for hydrogen generation and PEM fuel cells for hydrogen utilization. Both technologies are crucial to achieve the EU’s ambitious targets for the transition of the energy system to fluctating renewable energy soucres, specifically solar and wind, as hydrogen is a very scalable form of energy storage. The EU’s targets are formulated in the European Green Deal as well as in the REPowerEU program with ambitious growth targets. While end of 2022 180 MW electrolysis was deployed in Europe, it is planned to increase this to 140 GW by 2030, i.e. a more than 700 fold increase, with a share of around 30 % for PEM technology. Such an increase in hydrogen generation is necessary to achieve climate targets and ultimate a net-zero society in view of carbon emissions: In September 2023, the „Royal Society“ postulated that „Even though green hydrogen has a poor round-trip efficiency of about 41 % — i.e., for every 100 MWh of renewable energy used to produce green hydrogen, only 41 MWh would be produced by a fuel cell consuming that H2 — and that this will lead to relatively high costs, other technologies will not be able to offer the scale of energy storage required.” (source: 'Seriously underestimated' | Vast amounts of hydrogen will be required for back-up power in net-zero system: study | Hydrogen news and intelligence ) Yet, both PEM electrolysers and PEM fuel cells rely strongly on fluoropolymers, mainly polytetrafluoroethylene (PTFE) and perfluorosulfonic acids (PFSAs) polymers, both a type of PFAS. As of today, there is no adequate substitution which fulfills the requirements, especially of durability, under the harsh environments of these applications characterized by high temperature, pressure, acidity, electrochemical potentials or radicals formed on catalytic surfaces. PFSA materials are used as membrane material between the electrodes because of their high proton conductivity even under dry operation conditions, as well as the catalyst binder within the electrodes. PTFE is used a reinforcement structure for the membrane, as a binder in the microporous layer of the gas diffusion layer (GDL), and in sealing structures. Moreover, PTFE-based materials are used in the production processes, e.g. in hot presses or as coating substrates for electrodes, because of the low surface energy and excellent release properties. The final product is called a catalyst coated membrane (CCM) or membrane electrode assembly (MEA). Without fluoropolymers, there is no PEM electrolysers and PEM fuel cells and ambitious climate targets and decarbonization of the society will not be possible. PEM electrolysis is the key technology to achieve sector coupling and enabling the use of renewable energy not only for electricity, but also for industrial applications, in the chemical and steel industry, for heating and heat generation, and mobility including various field like heavy duty trucks, maritime application and in the future also aviation. Therefore, we would like to propose a no time limited derogation for fluoropolymers in the hydrogen industry encompassing PEM electrolysis and PEM fuel cell. Yet, it could be considered to review the status of PFAS-free alternatives periodically after entry into force of the PFAS restriction, e.g. every 5 years, and revise the derogation to time limited version accordingly. Unfortunately, the present restriction proposal missed to clearly grasp the information on the importance of fluoropolymers especially for PEM water electrolysis. While there is a certain understanding for PEM fuel cells – resulting in a proposed derogation of 5 years – Table E.134 (p. 416 of Annex E) mentions that no information has been received for PEM electrolysers. Considering the input just one line above in the same table (i.e. “Another stakeholder: While conduction properties and performance of these materials can be reasonably good, mechanical stability and durability are extremely poor, as oxidation by oxygen radicals, occurs. All nonfluorinated membrane concepts are still highly immature against minimum lifetime requirements of more than 25 000 hours. Although there would be an economic advantage to finding performant fluorine-free materials, there is no alternative today to replace PFASs (PFSA, PTFE) in the hydrogen industry (both electrolyser and fuel cell).” as well as Greenerity’s own submissions in the first and second call for evidence, it is obvious that not all provided information could be processed in a complete manner. From a technical point of view, both technologies for hydrogen utilization (PEM fuel cell) and hydrogen generation (PEM electrolyser) should be exempted from the proposed PFAS ban, with an even higher importance of PEM electrolyser due to the versatile application scenarios of hydrogen in the whole economy, which is vital for sector coupling. Notably, the beforementioned technologies, which are a key enabler for the utilization of fluctuating renewable energy, use exclusively a very special type of PFAS materials, i.e. fluoropolymers. Analysis of the risk profiles of fluoropolymers demonstrated that most of them meet the definition of “polymers of low concern” according to the OECD. Fluoropolymers are not water soluble, not bioaccumulative and non-toxic. Accordingly, most fluoropolymers do not represent a risk to human health or the environment as such. The sole risk is there inherent stability – a key in the intended applications – which results in persistency once emitted to the environment. Therefore, it is important to analyse carefully the way these fluoropolymers are manufactured and later on processed and employed in the specific application. Manufacturers of fluoropolymers of course rely on PFAS-type monomers, e.g. tetrafluoroethylene (TFE), a volatile and toxic substance. Yet, best practice handling, state of the art waste stream have proven to suppress air and water borne emission to a minimum, removing more then 99,99 % of emissions. Manufacturing of CCMs and MEAs using those fluoropolymers occurs in an extremely controlled environment and emission measurements during the production processes have shown that no PFAS emission during coating and lamination of fluoropolymers at the typical processing temperatures below 200 °C occurs. Waste (Scrap) originating from the production is collected in special waste and disposed conforming to legal requirements. Accordingly, no emissions to the environment are expected from the manufacturing process. (0 %) Treatment of the waste depends on the presence of precious metal. Precious metal and fluoropolymer containing waste is treated through incineration (~ 20 %; i.e. end of life of the product), to recover the precious metal components, especially Platinum and Iridium. Pure fluoropolymer waste (~80 %; i.e. process material) is treated through landfill in agreement with the German “Verordnung über das Europäische Abfallverzeichnis (AVV)“ The use of PEM electrolysers and PEM fuel cells happens in so called stacks, or systems, which are encapsulated hardware systems and are not expected to emit fluoropolymers to the environment. It is currently an intense object of research and industrial effort to demonstrate that no PFAS containing emissions occur due to degradation of the fluoropolymers in CCMs or MEAs during the use. Expected degradation product of fluoropolymers should be anionic fluoride ions, which are the natural from fluorine and therefore do not pose a risk to the environment. From the socio economic standpoint, recent studies (Hydrogen Council & McKinsey & Company, 2023; https://hydrogencouncil.com/wp-content/uploads/2023/05/Hydrogen-Insights-2023.pdf) expect a global increase of electrolyser capacity by a factor of 300 from the year 2022 to the year 2030, resulting in ~232 GW expected capacity, of which around 50 % might be PEM electrolysis. This demonstrates not only the need for this technology to produce hydrogen, but also a major economic impact which is expected to lead to cumulated investments of 300 billion EUR by the year 2030 for electrolyser technology alone. |
| Answer to specific info request 1:  Energy sector |
| Answer to specific info request 3:  In view of incineration of fluoropolymers, two recent publication shall be cited. Aleksandrov et al. (Chemosphere 2019) (https://www.sciencedirect.com/science/article/pii/S0045653519306435) could show that „Municipal incineration of PTFE shows no significant generation of studied PFAS.“ and that incineration of „PTFE produced mainly hydrofluoric acid and carbon dioxide during incineration.“ Furthermore, their „results give no significant evidence that the PFAS studied were created during the incineration of PTFE could be found.“ Also Wang et al. (Environmental Science & Technology, 2022) (https://www.sciencedirect.com/topics/earth-and-planetary-sciences/sewage-treatment) came in an extensive study to the conclusion that „it can be expected that municipal incineration of PTFE using best available technology is not a significant source of studied PFAS and should be considered an acceptable form of waste treatment.” |
| Answer to specific info request 5:  Information will be covered in "SECTION V. Confidential Attachment" |
| Answer to specific info request 8:  Information will be covered in "SECTION V. Confidential Attachment" |

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| 8746 | Date:  2023/09/22 15:55  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Protection of our commercial interests, including intellectual property. | General Comments:  Our company supports reasonable activities and measures to prevent potential risk and protect the environment and human health and fully agrees with the dossier submitters that the emission of demonstrably harmful substances should be prevented due to their lasting global impact on environment and organisms. However, we disagree with a blanket ban of a substance group of over 10 000 substances as this does not meet the requirements of a risk-based assessment and is therefore not reconcilable with Article 68 of the REACH Regulation. In many cases, especially concerning fluoropolymers, the use-phase is admittedly unproblematic. Safe industrial uses of fluoropolymers where the risks can be controlled by appropriate measures via occupational safety, emission control or waste legislation must remain available. For issues that arise from the production and end-of-life-phase, appropriate measures should rather be regulated via waste legislation or emission control instead of a general ban. Our main concern is a possible broad and short-termed restriction with serious downstream consequences, mainly endangering the availability of extremely relevant high-tech materials, technologies and products made in Europe. Affected are many materials with relevance to numerous varying national and international product quality standards (e.g., electrical insulation, UV exposure, tracking resistance, temperature resistance, fire resistance etc.). Modification of the material composition will require a time-consuming re-design and re-qualification with new approvals and testing for thousands of materials, components, and articles to guarantee that the requirements for technical and human safety are met. Recertification will therefore take a large share of additional cost, time, and effort for substitution of the products along the whole supply chain. These efforts are to be expected by the companies themselves as well as the certification bodies, laboratories, and authorities since the requirement will be needed at the same time for the entire industry in Europe. This will contribute to resource shortages, supply bottlenecks and possible allocations and will put the industry under severe pressure. With the complexity of the products and supply chains in the E&E sector, as well as the large number of substances that are proposed to be restricted, there is a risk that despite the huge determination efforts applications of PFAS will remain undiscovered and subsequently turn out to be relevant. As a downstream user and manufacturer of articles, we are in the middle of the supply chain and rely on statements and knowledge of our suppliers for thousands of components but also on the alternative possibilities and aspirations of the material manufacturers. There is still missing information on PFAS in products in the European and global supply chain as there is no declaration or information obligation for products according to REACH Article 33 for all PFAS substances and no uniform legal basis at international level, which also weakens the influence and control over EU imports. A complete, gapless risk assessment for manufacturers of complex articles and an endless number of substances at a time when the legislation is not yet in force is practically impossible, as the information in the supply chain is not yet available, know-how protected and not mandatory to declare, which means that it is also not available or provided in the supply chain even upon request. Since the concrete requirements of the PFAS restriction proposal have only been announced in February 2023 and the outcome of the PFAS restriction proposal is not yet clear, which means that the specific conditions remain changeable, there will be difficulties to start with full substitution of all products through the entire supply chain and timely enforcement of the requirements within the short deadlines that the dossier submitter have proposed for the restriction. The situation is similar for industrial machines and systems, where PFAS containing materials are indispensable as extremely relevant seals, valves, lubricants, or hoses, where we also expect sudden material and producing performance failure through the years. Assumption for a development and qualification of a new product is a technically suitable alternative with similar performance which, according to our knowledge based on supplier requests and conversations as well as information exchange with several European and international associations is currently not fully available for fluoropolymers on the market for all applications. It should be noted that new solutions are mostly niche products, which are normally produced in much smaller volumes with less capacities, so additional shortages and supply bottlenecks must be expected in the material manufacturing industry. Considering the wide use of fluoropolymers in the industry, there is a high risk of a domino effect with similar consequences multiplied along the supply chain. This has been confirmed by the enormous participation in the public consultation of the current universal PFAS restriction proposal. Although our products are less affected by the restriction of low-molecular PFAS, we want to emphasise that E&E companies depend on material that is produced with the help of such substances, e.g., fluoropolymers and semiconductors. With the displacement of the respective manufacturers for such materials from the EU, the E&E industry will have to rely exclusively on non-EU suppliers. In analogy to regrettable substitution, this outcome is very undesirable since the production will then be beyond the influence of the EU while potential emission of PFAS still affects the shared environment.  Our request on the PFAS restriction proposal: Due to the wide industrial application of PFAS in combination with the specific characteristics of the substances we believe that a general ban would seriously endanger European production and development sites as well as their global competitiveness. It requires more time to find suitable, effective substitutes for such numerous and technically specific applications, close information gaps and enable development re-design and re-certification for substitutes for existing applications or innovations. We therefore call for a fundamental revision of the restriction proposal and ask for consideration of the following aspects and key requirements of the current state of the PFAS restriction proposal:  a. Transition period of at least 48 months after entry into force to allow for the time-consuming re-design and re-certification of the product with available substitutes. b. Long-term derogation for the manufacturing and use of fluoropolymers of “low concern” in safe industrial applications. c. Information obligation for "intentionally added" PFAS (e.g., by inclusion in the REACH Candidate List) to close information gaps about substances in articles. d. Concentration value of 1000 ppm of “intentionally added" PFAS for articles to exclude impurities. e. Procedure for renewal and re-applying of exemptions, to ensure important existing applications or innovations when substitution is not possible. f. General exemption for products already placed on the market to prevent unnecessary disposition of products and warrant use in complex products. g. General exemption for placing on the market of spare, wear and used parts to ensure sustainability and cost-effectiveness according to the repair-as-produced principle. h. Reporting obligation to the Agency within at least 48 months after entry into force in accordance with the transition period (Point 7 of the restriction proposal). |

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| 8747 | Date:  2023/09/22 15:55  Content:  Request for exemption  Type:  Individual  Country:  France | General Comments:  Nous fabriquons des cellules moyennes tensions (appareillages électriques 20KV) Nous utilisons une graisse contenant des PFAS de chez Kluber cette graisse est utilisée pour obtenir une étanchéité parfaite de nos produits. Sans cette graisse, nos produits qui ont normalement une durée de vie de plus de 20 ans, subiront des défauts interne lors de la première manœuvre au bout de 2 à 3 ans d'utilisation. nous n'avons pas à ce jour de solution de remplacement |
| Answer to specific info request 5:  Nous utilisons 80 kg par an |

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| 8748 | Date:  2023/09/22 15:57  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Razor Blades Manufacturers  Org. country:  Belgium  Attachment: | General Comments:  EPPA performed a detailed SEA (socio-economic analysis) and AoA (Analysis of Alternatives) for four major manufacturers of razor blades for shaving: BIC, Edgewell, Harry’s and Procter & Gamble (hereinafter Participating Manufacturers). The analysis focuses on specific PFAS used for blade edge coatings on razor blades in the European Economic Area (EEA) market. The Participating Manufacturers together hold a market share of 90 to 95% of the EEA razor blades market. The main purpose of this analysis is to provide regulators with strong evidence-based findings on the anticipated societal and economic impacts that are expected to occur should these substances be restricted under REACH. The analysis is submitted as a public attachment that contains a detailed description of the aims and scope of the analysis, perspectives on alternatives, as well as impacts, plus a conclusion, and the derogations justified by the analysis in this document. Based on the evidence-based impact assessment and analysis of alternatives presented in the attachment, a broad restriction for the use of PFAS in the manufacturing of blades and razors would lead to unacceptable costs for the European society and negatively impact the EU economy.  Based on the highly representative survey and the detailed SEA and AoA, the analysis presented in the attachment, therefore concludes that a broad restriction without a long-term derogation for the use of PFAS in the manufacturing of razor blades for shaving will have disproportionate negative impacts on the European economy and society. This report reasonably justifies the following request: - a derogation for the placing on the market of razor blades containing PFAS until 13.5 years after the entry into force, - a derogation for the manufacture, marketing, and use of PFAS and the placing on the market of substances, mixtures and articles containing PFAS to manufacture razor blades for shaving until 13.5 years after the entry into force.  Therefore, we request the following text to be included in the restriction: - By way of derogation, paragraphs 1 and 2 shall not apply to: Coatings in razor blades used for shaving until 13.5 years after the entry into force. - By way of derogation, paragraphs 1 and 2 shall not apply to: The manufacture of razor blades used for shaving until 13.5 years after the entry into force. |
| Answer to specific info request 1:  PTFE-coated razor blades are currently not covered in the Annex XV restriction report. PTFE coatings for surgical and cutting blades are covered in a potential derogation for reconsideration. Nevertheless, the Participating Manufacturer’s razor blades are for consumer use and it is unclear where they would fit in the current (sub-)uses classification. |
| Answer to specific info request 2:  Collectively, the Participating Manufacturers report that they purchase a total of 1,287 kg PTFE annually for their manufacturing of razors and blades in the EEA, of which 944 kg are purchased from EEA suppliers. Based on the received data and by making use of a weighted average, more than 50% of the purchased PTFE is used during the manufacturing of the blades. The remaining purchased quantity of PTFE remains on the final razor blades. As the PTFE coating is sprayed on the blades, only a fraction of the quantity used is deposited on blades. The sprayed mist that does not reach the blades and contains PTFE is entrapped in the closed spraying booth and finally is collected either as a solid residual waste or as an aqueous dispersion in liquid form for expired materials. Throughout the manufacturing process, emissions are controlled through the implementation of air filtration systems during the spraying procedure. Additionally, residual materials and empty raw materials containers are managed through cleaning and disposal procedures. Due to the closed system and use of appropriate personal protective equipment (PPE), worker exposure is avoided. These materials are subjected to thermal recycling in a municipal waste combustor. The Participating Manufacturers have ongoing research into more precision spraying, aimed at reducing the quantity of PTFE that does not reach the blade during spraying and thereby optimizing the transfer efficiency. There are no extensive studies available regarding the release, if any, of PFAS during product usage. The PTFE coating on the blades is designed to be well-adhered due to the strong chemical bonds with the surface of the blades. This ensures that the amount of PTFE that might potentially be released (if any) during the use-phase is limited. In the EU, household waste is either incinerated or landfilled. According to a 2019 study by Aleksandrov, et al., municipal incineration of PTFE does not result in measurable PFAS emissions at temperatures between 860 and 1,020 °C. According to the authors, the results confirm that when incinerated under representative European municipal incinerator conditions, fluoropolymers do not generate any measurable levels of PFAS emissions at their end of life and therefore pose no risk to human health and the environment. Furthermore, no PFAS emissions from PTFE coated razor blades are expected when they are landfilled. PTFE is chemically, thermally, and biologically stable and therefore PTFE coated razor blades are not expected to lead to dispersive non-polymeric PFAS when disposed of in a landfill (Korzeniowski, et al., 2023). Other studies have presented results from OECD guideline biodegradation studies, demonstrating that PTFE is stable and does not degrade under environmentally relevant conditions Furthermore, fluoropolymers that meet the criteria to be considered PLC have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing and would therefore not be expected to significantly contribute to landfill leachate. (Henry, et al, 2018 & Ruwona, 2021). Given the above, the end-of-life stage from coated razor blades is not expected to lead to PFAS emissions. The public attachment to this submission titled “PUBLIC\_RazorBlades\_PFAS\_Public-Consultation-Document\_2023-09-21’’ provides further evidence on the projected emissions at the end-of-life phase. References: 1. Aleksandrov, K., Gehrmann, H.J., Hauser, M., Mätzing, H., Pigeon, D., Stapf, D. and Wexler, M., 2019. Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per-and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Chemosphere, 226, 898-906. 2. Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. Integrated Environmental Assessment and Management, 19(2), 326-354. 3. Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management, 14(3), 316-334. 4. Ruwona, T., 2021. The fluoropolymer PTFE is stable at environmentally relevant temperatures. In 2021 Emerging Contaminants in the Environment Conference (ECEC21). |
| Answer to specific info request 3:  As the PTFE coating is sprayed on the blades, only a fraction of the quantity used is deposited on blades. The sprayed mist that does not reach the blades and contains PTFE is entrapped in the closed spraying booth and finally is collected either as a solid residual waste or as an aqueous dispersion in liquid form for expired materials. Throughout the manufacturing process, emissions are controlled through the implementation of air filtration systems during the spraying procedure. Additionally, residual materials and empty raw materials containers are managed through cleaning and disposal procedures. Due to the closed system and use of appropriate personal protective equipment (PPE), worker exposure is avoided. These materials are subjected to thermal recycling in a municipal waste combustor. The Participating Manufacturers have ongoing research into more precision spraying, aimed at reducing the quantity of PTFE that does not reach the blade during spraying and thereby optimizing the transfer efficiency. There are no extensive studies available regarding the release, if any, of PFAS during product usage. The PTFE coating on the blades is designed to be well-adhered due to the strong chemical bonds with the surface of the blades. This ensures that the amount of PTFE that might potentially be released (if any) during the use-phase is limited. At the end-of-life, the Participating Manufacturers have indicated that consumers dispose of their used razor blades as part of their household waste. Razor blades can be therefore assimilated to the so called “Municipal solid waste (bin/trash) disposal," which was defined by the Risk Assessment Committee, in its opinion on the Microplastics restriction proposal, as a pathway to the environment with rather low risk of emissions. In the EU, household waste is either incinerated or landfilled. According to a 2019 study by Aleksandrov, et al., municipal incineration of PTFE does not result in measurable PFAS emissions at temperatures between 860 and 1,020 °C. According to the authors, the results confirm that when incinerated under representative European municipal incinerator conditions, fluoropolymers do not generate any measurable levels of PFAS emissions at their end of life and therefore pose no risk to human health or the environment. Furthermore, no PFAS emissions from PTFE coated razor blades are expected when they are landfilled. PTFE is chemically, thermally, and biologically stable and therefore PTFE coated razor blades are not expected to lead to dispersive non-polymeric PFAS when disposed of in a landfill (Korzeniowski, et al., 2023). Other studies have presented results from OECD guideline biodegradation studies, demonstrating that PTFE is stable and does not degrade under environmentally relevant conditions Furthermore, fluoropolymers that meet the criteria to be considered PLC have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing and would therefore not be expected to significantly contribute to landfill leachate. (Henry, et al, 2018 & Ruwona, 2021). Given the above, the end-of-life stage from coated razor blades is not expected to lead to PFAS emissions. The public attachment to this submission titled “PUBLIC\_RazorBlades\_PFAS\_Public-Consultation-Document\_2023-09-21’’ provides further evidence on waste management. References: 1. ECHA, 2020. Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC - Opinion on an Annex XV dossier proposing restrictions on intentionally-added microplastics. Available at: https://echa.europa.eu/documents/10162/a513b793-dd84-d83a-9c06-e7a11580f366 (Accessed in July 2023). 2. Aleksandrov, K., Gehrmann, H.J., Hauser, M., Mätzing, H., Pigeon, D., Stapf, D. and Wexler, M., 2019. Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per-and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Chemosphere, 226, 898-906. 3. Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. Integrated Environmental Assessment and Management, 19(2), 326-354. 4. Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management, 14(3), 316-334. 5. Ruwona, T., 2021. The fluoropolymer PTFE is stable at environmentally relevant temperatures. In 2021 Emerging Contaminants in the Environment Conference (ECEC21). |
| Answer to specific info request 6:  PTFE-coated razor blades are currently not covered in the Annex XV restriction report. PTFE coatings for surgical and cutting blades are covered into a potential derogation for reconsideration. Nevertheless, the Participating Manufacturer’s razor blades are for consumer use and it is not clear where they would fit in the current (sub-)uses classification. The Participating Manufacturers are major players in the EEA as well as in the global razor blades markets. They have an aggregate revenue related to the sales of blades and razors of more than 1.3 billion EUR in the EEA market and have various manufacturing plants for blades and razors in the EEA, specifically in the Czech Republic, France, Germany, Greece, and Poland. These EEA sites produce more than 11 billion cartridges and disposable razors each year with approximately 50% being exported out of EEA. The Participating Manufacturers use PTFE to obtain a thin coating on the razor blade edges. To achieve this thin layer of PTFE, the Participating Manufacturers spray a PTFE material onto the blade edges. To ensure there is a well-adhered, continuous coating on the edge of the blade, the blades are heated to sinter the PTFE particles. The key characteristic of the PTFE coating on the blade edge is its low coefficient of friction. This contributes to a reduction in hair cutting force, which ultimately translates in a more safe, comfortable, and smooth shaving experience. Blades with the PTFE coating demonstrate a reduction of up to 70% in cutting force versus those without the PTFE coating. A suitable alternative to the PTFE coating on the blade edges must have a low coefficient of friction, must be highly inert, durable, thin, and cost-effective. There is currently no evidence of any technically suitable, economically feasible, and readily available alternatives to PTFE-based coatings for razor blades that can provide comparable product performance benefits for shaving products and that could be deployed in the next 15 years. Dossier Submitters (DSs) have identified the presence of PFAS substances in the components of the powered, dry shaving products (such as membranes, batteries, and electronic circuit board). Therefore, it is unrealistic to anticipate that the market would transition towards powered, dry shaving products as these technologies would also be facing PFAS substitution challenges. Lower performing edge coatings, such as silicone oils and silicone-like materials are available. However, the performance of such coatings on a blade edge is significantly inferior, especially in terms of durability of performance (1-2 shaves only). Additionally, the processes used to coat blades using these silicone oils and silicone-like materials are typically non-durable and sensitive to changes in the processing conditions or substrate material, leading to widely variable edge performance. If consumers wanted a similar experience from products that do not contain PTFE, they would need to replace their razor blades products at more than 10 times the current average rate. As a result, there would be a significant increase in consumer waste and disposal of over 10 times more products, which could be an unintended negative consequence of the restriction on PTFE. The Participating Manufacturers would support the phase out of the use of PFAS where technically suitable and economically viable alternatives are available. However, phase-out requires the availability of technically suitable and economically viable alternatives. As discussed above, such technically feasible and economically viable alternatives do currently not exist. Substitution, in the event that an acceptable alternative is identified, developed, and/or validated, is a highly time-consuming process due to the complexity of the affected products. In any event, it will not be possible to find alternatives and substitute them for PFAS in blades and razors in the proposed 18-month transition period. If a suitable alternative coating to PTFE is found, current manufacturing equipment would need to be discarded and replaced with completely new equipment. Staff would need to be newly trained to operate it. Therefore, it is estimated that it could take approximately 15 years, and cost more than 132 million EUR, to develop and launch PFAS-free products that use an alternative to the PTFE coating. The total monetised impact of a PFAS restriction is calculated as more than 2.8 billion EUR in a 4-year horizon for the manufacturers of razor blades. This sum includes approximately 43 million EUR of economic impact driven by substitution costs for the manufacturers of razor blades; 2.5 billion EUR of economic impacts (EBIT losses) and 288 million EUR of social impact deriving from unemployment. This is a conservative (lower boundary) estimate. In the case of a restriction on PFAS (PTFE) used in the production of razor blades, the cost per kg of avoided PFAS (PTFE) emissions is estimated to be at least 149,541 EUR/kg for all releases for over 30 years (temporal scope chosen by DSs) under a conservative estimation on the emissions. This cost-effectiveness ratio is considered high enough to justify a time-limited derogation of at least 12 years (with an additional 18-month transition period, adding up to 13.5 years after the entry into force) for the use of critical PFAS, such as PTFE in razor blades and their production. The broad restriction of PTFE and the marketing of mixtures and articles containing PTFE in the EEA will have impacts on the competitiveness of the EEA markets for razor blades, on competition in the EEA, on innovation, and on the overall EEA trade balance. Non-EEA manufacturers would not be subject to a restriction of PFAS used in manufacturing equipment and production processes. As a result, the attractiveness of the EEA for investment in innovation and R&D would be jeopardised. Based on the highly representative survey and the detailed SEA and AoA, the report concludes that a broad restriction without a long-term derogation for the use of PFAS in the manufacturing of razor blades for shaving will have disproportionate negative impacts on the European economy and society. This report reasonably justifies the following request: a derogation for the placing on the market of razor blades containing PFAS until 13.5 years after the entry into force; a derogation for the manufacture, marketing, and use of PFAS and the placing on the market of substances, mixtures and articles containing PFAS to manufacture razor blades for shaving until 13.5 years after the entry into force. Therefore, we request the following text to be included in the restriction: - By way of derogation, paragraphs 1 and 2 shall not apply to: Coatings in razor blades used for shaving until 13.5 years after the entry into force. - By way of derogation, paragraphs 1 and 2 shall not apply to: The manufacture of razor blades used for shaving until 13.5 years after the entry into force. The public attachment to this submission titled “PUBLIC\_RazorBlades\_PFAS\_Public-Consultation-Document\_2023-09-21’’ provides further evidence and motivation on the impacts of a restriction on the EEA razor blades market. |

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| 8749 | Date:  2023/09/22 15:59  Content:  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  We considered this attachment as confidential as it contains some confidential business internals. | General Comments:  The information in this consultation paper relates to our Analytical Technology business unit.  Our company develops, manufactures, and distributes specialized components and system solutions for the gas analysis and hydraulics markets. With more than 150 employees in Germany and subsidiaries in Asia, the USA, France and other partner networks, we supply our customers worldwide from our manufacturing site in Germany. Our products monitor, control and optimize our customers' industrial processes and keep track of the emission monitoring requirements. They promote sustainable, climate-friendly production processes and the efficient use of energy resources.  -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 1:  Our products are important for other markets such as power and energy, oil and gas, chemicals and petrochemicals, marine equipment, etc. But a specifying sector for industrial sample gas conditioning and gas analysis is not listed in Annex XV. |
| Answer to specific info request 2:  No emissions are expected during the lifetime of our products. -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 4:  Our products are produced and used exclusively for B2B customers. At the end of the product's life, end-of-life devices and components are not disposed of with general municipal waste. The disposal or recycling is carried out by official waste management companies. -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 5:  -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 6:  -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 8:  We do not comment on this section. Some of the information requested here is already presented in our contribution in Section 6. |

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| 8750 | Date:  2023/09/22 15:58  Content:  Scope or restriction option analysis  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Watson-Marlow Fluid Technology Solutions  Org. country:  United Kingdom  Attachment:  <redacted>  Privacy statement:  The attached document contains information confidential to Watson-Marlow Fluid Technology Solutions. | General Comments:  Please see the confidential attachment detailing Watson-Marlow Fluid Technology's assessment of non-PFAS surfactant PTFE material processing for tubing. This submission is intended to supplement Watson-Marlow Fluid Technology Solution's initial comments and report submitted on 28th April 2023, reference number 052628a1-3d5d-48b7-929e-4a9f3a4b4b26. |

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| 8751 | Date:  2023/09/22 16:01  Content:  Environmental emissions  Information on alternatives  Information on benefits  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 1:  Metal plating and manufacture of metal products Hard chromium plating |
| Answer to specific info request 2:  The company uses an average of 250 kg of solution with PFAS/year, a very small quantity indeed when compared with figures quoted in the annex XV report. According to the SDS, the solution of fume suppressant used by the company contains between 2,5 and 3% (w/w) of the following PFAS. Name: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonic acid CAS number: 27619-97-2 EC number: 248-580-6 the emmisions of the PFAS used is under the limit of detection, we have stimated 4 gr for year (overstated) |
| Answer to specific info request 3:  we dispose of about 30000 kg of waste between washing water contaminated with chromic acid and chromium-plating sludge. the percentage of PFAS within this waste is 0,03 % (overestimated calculation) |
| Answer to specific info request 5:  The company uses an average of 250 kg of solution with PFAS/year, a very small quantity indeed when compared with figures quoted in the annex XV report. According to the SDS, the solution of fume suppressant used by the company contains between 2,5 and 3% (w/w) of the following PFAS: Name: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonic acid CAS number: 27619-97-2 EC number: 248-580-6 the emmisions of the PFAS used is under the limit of detection, we have stimated 4 gr for year (overstated) we dispose of about 30000 kg of waste between washing water contaminated with chromic acid and chromium-plating sludge. the percentage of PFAS within this waste is 0,03 % (overestimated calculation) The total amount of PFAS used in one year is about 8 kg (a very small quantitative) |
| Answer to specific info request 7:  The company asks for a derogation of at least 5 years for the use of PFAS as fume suppressant in the hard chrome plating. In support of this claim the company submits the following information. Mission of the company: The company is a functional chrome plating shop with the size of a SME. The mission of the company is providing the customer with top quality coatings, quickly and at a competitive cost while being compliant with each of the laws established to protect human health and protect the environment. According with the mission, the company benefits of the authorization granted on 18th December 2020 to Chemservice GmbH and others (CTACSub) for the use of chromium trioxide for functional chrome plating (Use 2). The company notified to ECHA the use of chromium trioxide and made available in the due time the information collected from monitoring programmes. The company contributed to the review report submitted to ECHA on 21st February 2023 by the CTACSub2. About availability of suitable alternatives: The company has no financial resources or scientific expertise to carry out own scientific research. Nonetheless, the company has always been available for testing alternatives proposed by different suppliers of chemicals. At the time there is no valid sostitution of this fume suppressant Annual use of PFAS: The company uses an average of 250 kg of solution with PFAS/year, a very small quantity indeed when compared with figures quoted in the annex XV report. According to the SDS, the solution of fume suppressant used by the company contains between 2,5 and 3% (w/w) of the following PFAS: Name: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonic acid CAS number: 27619-97-2 EC number: 248-580-6 Emissions of PFAS: the emmisions of the PFAS used is under the limit of detection, we have stimated 4 gr for year (overstated) we dispose of about 30000 kg of waste between washing water contaminated with chromic acid and chromium-plating sludge. the percentage of PFAS within this waste is 0,03 % (overestimated calculation) The total amount of PFAS used in one year is about 8 kg (a very small quantitative indeed when compared with figures quoted in the annex XV report) |

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| 8752 | Date:  2023/09/22 16:01  Content:  Scope or restriction option analysis  Information on alternatives  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Topsoe  Org. country:  Denmark  Attachment: | General Comments:  Please see the attachement for the elaborate Topsoe statement. |
| Answer to specific info request 1:  Missing sector:  Chemical industry |
| Answer to specific info request 3:  Currently the waste handling of fluoropolymer coated spare parts can be split up into two streams. The tougher materials such as heat exchangers are shredded and separated based on metal type. The metal is recycled, and any other material is sent for incineration. The softer materials such as personal protective equipment are sent for waste incineration. |
| Answer to specific info request 6:  As shown in table A.1 of Annex A to the proposal, the chemical industry has not been researched in detail. Hence the importance of emphasizing the necessity of fluoropolymers covered by this proposal.  A) Topsoe cannot provide a tonnage range for PFAS as we use fluoropolymers in the form of coated equipment from our suppliers.  Based on a survey of all Topsoe’s equipment suppliers, the vast majority of fluoropolymer suppliers cannot provide emission data to us (e.g., leakage, degradation,…). However, due to the chemical and thermal stability of fluoropolymers, this is not expected either.  B) Fluoropolymers enables Topsoe to operate in harsh chemical and thermal conditions unmatched by any other substance. They provide durability and ensure that our production processes stay closed systems. As Topsoe utilizes known hazardous chemicals, fluoropolymers provide exposure protection to our employees and the environment.  C) Topsoe expects every chemical company that utilizes closed chemical systems with hazardous chemicals, such as us, to be affected by this ban. Based on the CEFIC report Topsoe participated in, at least 111 companies have these systems.  D) To quote the fluoropolymer application part of the petroleum and mining section in table 9 of the proposal: “In light of the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a derogation is proposed for: Fluoropolymer applications”. It is clear to the proposers that substitution is not feasible. If technical alternatives can be found, regrettable substitution must be avoided by holding these alternatives to the highest safety and environmental criteria.  E) Topsoe does not manufacture PFAS but relies on suppliers to find alternatives for fluoropolymer coated equipment. A survey of all Topsoe’s equipment suppliers resulted in over 3/4 of respondents believing there are no alternatives currently available, and they do not believe alternatives will be developed on a short-term basis.   F) Currently, substitution of fluoropolymers is technically not feasible (see point D).  G) Substitution of fluoropolymers is technically not feasible now. Estimating the socio-economic impact of a hypothetical alternative is not possible. If an alternative can be found that is technically comparable and does not compromise on hazardousness for humans and the environment, we will rely on the free market to offer these at a reasonable price. |

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| 8753 | Date:  2023/09/22 16:00  Content:  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  Individual  Country:  Germany | General Comments:  As a private individual, I welcome the ongoing discussion regarding the potential regulations for PFAS. In my view, regulatory intervention seems to be necessary since economic organisations have repeatedly demonstrated their lack of intrinsic motivation to manage potential risks to people and nature in a responsible and sustainable manner.  The measures included in the proposal could have significant implications for several companies, industries, and the European Union’s economic position. The exceedingly brief transitional periods for various sectors seem unfeasible to manage. Additionally, the categorisation of industries and subgroups appears overly broad, with some not or inadequately covered. The socio-economic assessment is affected by the broad classification.  I urge the ECHA commission to assess thoroughly and objectively nuclear power plants as on industy/group, with particular emphasis on their safety. It must be ensured that precise, concise and coherent information is available on nuclear energy and its application, which is regarded as the most hazardous and detrimental technology in existence. |

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| 8754 | Date:  2023/09/22 16:01  Content:  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  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  KROHNE Ltd.  Org. country:  United Kingdom  Attachment:  <redacted>  Privacy statement:  The protection of our commercial interests and IP would be undetermined, if the attachment would be made available to the public. E.g., exploded view drawings, technical details and some facts and figures. | General Comments:  KROHNE supports the objective of avoiding emissions of hazardous substances into the environment. The KROHNE Group is a global manufacturer and provider of process instrumentation, measurement solutions and services in many industries. Founded in 1921 and headquartered in Duisburg, Germany. The turnover in 2022 was 731.1 Mio. EUR (incl. joint ventures). Around 4.000 employees work for KROHNE in 15 production facilities in 10 countries worldwide. We request derogations, as follows:  1. Incorporation of process Instrumentation equipment as a missing use. 2. Spare parts and refurbished products must in principle be exempted from the restriction. 3. The repair-as-produced principle must be applied to the placing on the market of spare parts, wear parts and used parts. Especially in process industry 30 years use time is typical and therefore spare-parts in approved/certified equipment must be available. 4. Fluoropolymers should be considered as “Polymers of Low Concern” (PLC) and therefore • excluded from the restriction or • have a 12-year derogation for use in process Instrumentation equipment with review option for prolongation, if no suitable substitutes are found. |
| Answer to specific info request 1:  Electronics and semiconductors, Power & Energy, Lubricants, Petroleum and mining, Food contact materials and packaging - Industrial food and feed production are important for process instrumentation equipment applications are not sector specific. Therefore process instrumentation equipment has to be treated as a use sector of its own. Alternatively all following markets have to be added among others as use sectors: Power and energy, Nuclear power, District energy and building automation, Industrial gases, Food and beverage, Chemicals and petrochemicals, Oil and gas, Pharmaceuticals and biotechnology, Marine, Water and wastewater, Pulp and paper, Minerals and mining. |
| Answer to specific info request 2:  No emission is expected during life time. Process instrumentation equipment products are B2B and don´t end in private household waste. Controlled recycling is likely. Professional recycling is standard as required by WEEE directive using take back schemes |
| Answer to specific info request 3:  Professional recycling is standard as required by WEEE directive using take back schemes. |
| Answer to specific info request 6:  a. Process instrumentation equipment applications are not sector specific and therefore Process instrumentation equipment has to be treated as a use sector of its own (see 1) Annual tonnage in KROHNE factories in EU: 28t/year. Process instrumentation equipment industry is estimated to be 400t/year, based on a KROHNE market share of 7%. b. typical FP requirements/applications: temperature resistance, chemical resistance, low friction, long life, excellent sealing, low emissions, flame retardant, low dielectric constant, lipophobic & hydrophobic. |
| Answer to specific info request 8:  State of the art: No alternatives exist: It is important to enable EU companies to meet their obligations under the Green Deal and to continue to fulfill essential safety requirements of EU product safety directives. This requires a risk-based approach in the PFAS regulation. |
| Answer to specific info request 10:  For the majority of the 10000 PFAS there are no specific analytical methods available today. The extremely low limits of 25 ppb and 50 ppm for a large number of regulated PFASs cannot be reliably enforced in global, branched supply chains. |

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| 8755 | Date:  2023/09/22 16:03  Content:  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  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  KROHNE SAS  Org. country:  France  Attachment:  <redacted>  Privacy statement:  The protection of our commercial interests and IP would be undetermined, if the attachment would be made available to the public. E.g., exploded view drawings, technical details.... | General Comments:  KROHNE supports the objective of avoiding emissions of hazardous substances into the environment. The KROHNE Group is a global manufacturer and provider of process instrumentation, measurement solutions and services in many industries. Founded in 1921 and headquartered in Duisburg, Germany. The turnover of the KROHNE group in 2022 was 731.1 Mio. EUR (incl. joint ventures). Around 4.000 employees work for KROHNE in 15 production facilities in 10 countries worldwide. We request derogations, as follows:  1. Incorporation of process Instrumentation equipment as a missing use. 2. Spare parts and refurbished products must in principle be exempted from the restriction. The repair-as-produced principle must be applied to the placing on the market of spare parts, wear parts and used parts. Especially in process industry 30 years use time is typical and therefore spare-parts in approved/certified equipment must be available. 3. Fluoropolymers should be considered as “Polymers of Low Concern” (PLC) and therefore - excluded from the restriction or - have a 12-year derogation for use in process Instrumentation equipment with review option for prolongation, if no suitable substitutes are found. |
| Answer to specific info request 1:  Electronics and semiconductors, Power & Energy, Lubricants, Petroleum and mining, Food contact materials and packaging - Industrial food and feed production are important for process instrumentation equipment applications are not sector specific. Therefore process instrumentation equipment has to be treated as a use sector of its own. Alternatively all following markets have to be added among others as use sectors: Power and energy, Nuclear power, District energy and building automation, Industrial gases, Food and beverage, Chemicals and petrochemicals, Oil and gas, Pharmaceuticals and biotechnology, Marine, Water and wastewater, Pulp and paper, Minerals and mining. |
| Answer to specific info request 2:  No emission is expected during life time. Process instrumentation equipment products are B2B and don´t end in private household waste. Controlled recycling is likely. Professional recycling is standard as required by WEEE directive using take back schemes |
| Answer to specific info request 3:  Professional recycling is standard as required by WEEE directive using take back schemes. |
| Answer to specific info request 6:  a) Process instrumentation equipment applications are not sector specific and therefore Process instrumentation equipment has to be treated as a use sector of its own (see 1) Annual tonnage in KROHNE factories in EU: 28t/year. Process instrumentation equipment industry is estimated to be 400t/year, based on a KROHNE market share of 7%. b) typical Fluoropolymers requirements/applications: temperature resistance, chemical resistance, low friction, long life, excellent sealing, low emissions, flame retardant, low dielectric constant, lipophobic & hydrophobic. |
| Answer to specific info request 8:  State of the art: No alternatives exist: It is important to enable EU companies to meet their obligations under the Green Deal and to continue to fulfill essential safety requirements of EU product safety directives. This requires a risk-based approach in the PFAS regulation. |
| Answer to specific info request 10:  For the majority of the 10000 PFAS there are no specific analytical methods available today. The extremely low limits of 25 ppb and 50 ppm for a large number of regulated PFASs cannot be reliably enforced in global, branched supply chains. |

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| 8756 | Date:  2023/09/22 16:07  Content:  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  We considered this attachment as confidential as it contains some confidential business internals. | General Comments:  The information in this consultation paper relates to our Fluidcontrol business unit.  Our company develops, manufactures, and distributes specialized components and system solutions for the gas analysis and hydraulics markets. With more than 150 employees in Germany and subsidiaries in Asia, the USA, France and other partner networks, we supply our customers worldwide from our manufacturing site in Germany. Our products monitor, control and optimize our customers' industrial processes and keep track of the emission monitoring requirements. They promote sustainable, climate-friendly production processes and the efficient use of energy resources.  -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 1:  Our products are important for other markets such as power and energy, oil and gas, chemicals and petrochemicals, marine equipment, etc. But a specifying sector for industrial sample gas conditioning and gas analysis is not listed in Annex XV. |
| Answer to specific info request 2:  No emissions are expected during the lifetime of our products. -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 4:  Our products are produced and used exclusively for B2B customers. At the end of the product's life, end-of-life devices and components are not disposed of with general municipal waste. The disposal or recycling is carried out by official waste management companies. -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 5:  -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 6:  -- Please see the details in the confidential annex. We keep them confidential as some confidential business internals are covered. -- |
| Answer to specific info request 8:  We do not comment on this section. Some of the information requested here is already presented in our contribution in Section 6. |

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| 8757 | Date:  2023/09/22 16:08  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  National Authority  Org. name:  Swedish Food Agency  Org. country:  Sweden  Attachment: | General Comments:  - |

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| 8758 | Date:  2023/09/22 16:09  Content:  Scope or restriction option analysis  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  VDMA e. V. Textile Machinery  Org. country:  Germany  Attachment:    <redacted>  Privacy statement:  The confidential attachment contains detailed information about PFAS functional components, that are used in textile machines together with the justification of important properties that require PFAS components. This knowhow delivered by our member companies should not made public to protect their commercial interests. | General Comments:  We submit today revised versions of the non-confidential part and the confidential part of our comments (first version was submitted on August 23). The general comments remain valid unchanged. Our reference number is cf3be8e8-8067-4b5a-bcd4-1a326025423b |
| Answer to specific info request 6:  We submit revised versions of the non-confidential part and the confidential part of our comments (first version was submitted on August 23). The new documents contain information on more machines and components which are affected. Our reference number is cf3be8e8-8067-4b5a-bcd4-1a326025423b |

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| 8759 | Date:  2023/09/22 16:08  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Description of analytical methods  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Daikin Chemical Europe GmbH  Org. country:  Germany  Attachment: | General Comments:  Please refer to the non-confidential attachment. |
| Answer to specific info request 10:  Please refer to the non-confidential attachment. |

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| 8760 | Date:  2023/09/22 16:14  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  HLU GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  We upload the documents confidentially to protect business interests. | General Comments:  Machinery and equipment manufacturing industry is missing as a sector in the restriction proposal! We are producing product "fans for the chemical industry" and requesting for an exemption of PFAS application in the missed use "seals ind the industrial fans". |
| Answer to specific info request 6:  The information is submitted as an annex. |

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| 8761 | Date:  2023/09/22 16:15  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United States of America  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Demonstration of Commercial Interest: • Internal business information concerning technologies and development should be held away from competitors, thus it shall be treated as confidential. • Economic data related to turnover, employment and expected losses in case of a restriction scenario is confidential business information being part of the commercial strategies of the dossier submitter. This financial and commercial information meets all of the following requirements: (a) it is not publicly available or readily accessible to anybody except the decision makers at the dossier submitter (b) it has commercial value and constitutes an economic asset. Demonstration of Potential Harm: • Should it be shared with competitors, this disclosure could prejudice the competitive position of the dossier submitter in the conduct of its business. Information could be used by competitors, in conjunction with what is already known, to advance their position in the marketplace. Limitation to Validity of Confidentiality: • As a consequence, the information presented in the confidential attachment uploaded under section V. above should be protected indefinitely as confidential business information. | General Comments:  The dossier submitter manufactures articles for integrated systems applied to industrial automation equipment. Such equipment is critical for ensuring an increased efficiency, productivity, and precision at industrial production level as well as workplace safety in a variety of sectors in the EEA ranging from manufacturing, energy, aerospace to pharmaceuticals, water treatment and waste management, to mention only a few. Thus, the use of such articles indirectly contributes to the provision of essential resources and products (i.e., safe water and food, reliable energy, medicines, and electronic products, etc.) for the EEA society and its consumers.  For the manufacturing, maintenance, repair and overhaul of these articles, PFAS-containing products are required, namely: semiconductors; capacitors, electromechanical and electronic devices, and electronic boards; seals and gaskets; lubricants; lithium-ion batteries; flame retardants; wiring and cable insulation; flat panel displays; PTFE plastics (particularly resins); as well as further articles manufactured with PTFE for performance requirements due to harsh operational conditions (e.g., washer or tubes).  For the use of fluoropolymer-containing products in the manufacturing and MRO of articles for industrial automation, the dossier submitter requests a time unlimited derogation, given the lack of alternatives to fluoropolymers in these applications and the classification of fluoropolymers as polymers of low-concern. Meanwhile, for the use of products containing short chain PFASs, derogations are requested in accordance with the downstream users manufacturing the respective products (e.g., semiconductors, flat panel displays). Indeed, no alternatives are currently available to replace short-chain PFASs in such manufacturing processes. Overall, regarding the associated time derogations, the dossier submitter aligns with the derogations proposed by other industries active in the manufacture of the products in scope.  The dossier submitter would like to highlight that the omission of PFAS from the authorization list as a substance of very high concern, and the proposal to restrict it, significantly hinders the gathering of data on PFAS within the supply chain due to the constrained time period. Indeed, suppliers are not legally required to report information in their supply chain regarding PFAS substances. This leads to significant procedural challenges, as PFAS has so far remained unregulated, rendering the pertinent data virtually non-existent. The dossier submitter is conducting a survey throughout its upstream supply chain to gain a thorough understanding of the extent to which short-chain PFASs are used in products sourced from third-party suppliers. However, this is challenging due to the intricate nature of the supply chain and limited information from suppliers. Nonetheless, efforts are being made to collect as much data as possible.  With respect to the consequences that would be incurred within the EEA in case of a restriction scenario in which there would be no derogation for the use of PFAS-containing products for the manufacture and MRO of articles used in industrial automation, the present analysis reports on several socio-economic, sustainability and policy related implications. At the level of several stakeholders in the supply chain, such a restriction scenario would generate foregone profits, job losses as well as additional one-off investment costs for dismantling and clean-up of facilities following business shutdowns. Notably, for the purpose of monetization of impacts, due to data limitations, only foregone profits and the cost of unemployment associated with job losses at the dossier submitter could be quantified.  Beyond these monetized effects, the real impacts associated with a restriction scenario remain largely underestimated as broader societal and environmental consequences can only be qualitatively described due to lack of appropriate quantitative data. Such broader implications of a restriction include: a reduced operational productivity and safety coupled with reduced energy efficiency and consequently reduced market shares at the level of downstream industrial customers; a reduced shortage of essential products (clean water, medicines, safe food, renewable energy, electronics, etc.) on the EEA market as well as potentially increased prices for EEA consumers; significant delays for the electrification, sustainability and digitalization efforts and strategies at the EU level; a premature retirement of assets leading to a residual value of electrical and electronic equipment before end of life; an increased amount of electronic waste in the EEA; as well as foregone resources for producing equipment that does not reach end of life. |
| Answer to specific info request 1:  This derogation request concerns the use of PFAS-containing products for the manufacture and maintenance, repair, and overhaul (MRO) of articles (electrical and electronic equipment) for integrated systems applied to industrial automation. The dossier submitter manufactures electrical and electronic equipment as well as supporting accessories, housings, connectors and software applied as integrated systems to industrial automation processes. Non-exhaustive examples of industrial sectors relevant to the industrial automation systems manufactured by the dossier submitter include the aerospace, automotive, and marine industries; the agriculture sector; the chemical sector; the fibers and textiles sector; the food and beverages sector; the life sciences sector, including the pharmaceutical industry; the metal industry; the mining sector; the oil and gas industry; the pulp and paper industry; the energy sector, including the renewables segment; the electronics and semiconductors sector; the waste management sector, including the wastewater segment. The dossier submitter’s products are used for discrete, process, motion, and safety applications. Importantly, these applications involve very demanding operational conditions in industrial automation. These non-exhaustively include high temperature, strong mechanical forces leading to tear and wear, high pressures, aggressive chemical environments, etc. Such environments require the use of materials that can withstand them, hence, the incorporation of PFAS (mainly fluoropolymers). |
| Answer to specific info request 6:  Semiconductors require PFAS functionalities such as thermal and chemical stability, low surface energy, and material compatibility. Photoresist, Antireflective coatings, and Photolithography benefit from low surface energy and non-stick properties, whereas Developers and Etching rely on chemical stability and compatibility. Rinsing solutions benefit from moisture resistance and low flammability, while Vacuum pumps and Vapor phase soldering require heat resistance. Capacitors, electronic circuits, and related parts and electronic boards utilize PFAS for their water and moisture repellency, chemical stability, dielectric strength, solder resistance, and heat resistance. These properties help maintain the performance and durability of the components. In Lubricants, PFAS provide low friction, high-temperature stability, chemical stability, damping, and heat conductivity, contributing to smooth operation and reduced wear and tear. For Lithium batteries, PFAS play a crucial role in electrode binder and separator coatings by ensuring electronic and ionic conductivity, energy efficiency, and high durability. Additionally, they serve as additives for electrolytes to enhance conductivity and prevent corrosion. Flame retardants utilize PFAS for their high thermal stability, chemical stability, low surface energy, and non-stick properties, which help in suppressing fires and minimizing damage to materials. Wiring and cable insulation benefit from the chemical stability, heat resistance, low surface tension, and electrical insulation of PFAS, ensuring safe and reliable energy transmission. Flat panel displays use PFAS for chemical stability, selected reactivity, and low boiling points, enabling efficient display technology with a long lifespan. Seals and gaskets rely on PFAS for their chemical stability, temperature resistance, sealing properties, and adaptability to irregular surfaces, resistance to ultraviolet radiation, elevated pressures, and swelling, providing a secure and long-lasting seal. Further PTFE-based materials like washers and tubes depend on PFAS for flexibility, temperature stability, chemical resistance, durability, and transparency for monitoring. Finally, PTFE plastics (resins) require PFAS for their chemical resistance, low friction, reliable adhesion, and durability, ensuring a long-lasting and reliable material for various applications. Fluoropolymers (FPs) are crucial in various applications such as semiconductors, capacitors, electronic circuits, lubricants, lithium-ion batteries, flame retardants, seals, gaskets, wiring, and cable insulation. Their unique properties such as temperature and chemical resistance, low dielectric constant, and non-stick properties make it difficult to find alternatives. FPs are considered polymers of low concern, posing no health or safety hazards and contributing to economic growth. Industrial automation equipment relies heavily on FPs and short-chain PFAS due to their exceptional properties. Acquiring comprehensive data on short-chain PFAS usage is challenging since PFAS is not yet regulated, and suppliers are not legally obligated to report on PFAS substances. Given the difficulty of finding alternatives for certain applications and the potential negative impact on the EEA's industrial future, the dossier submitter requests a time-unlimited derogation for fluoropolymer-containing products. This approach allows industries to phase out PFAS, if possible, without imposing significant constraints, preventing potential shortages in essential goods. Meanwhile, for the use of products containing short chain PFASs, derogations are requested in accordance with the downstream users manufacturing the respective products (e.g., semiconductors, flat panel displays, etc.). Indeed, no alternatives are currently available to replace short-chain PFASs in such manufacturing processes. Overall, regarding the associated time derogations, the dossier submitter aligns with the derogations proposed by other industries active in the manufacture of the products in scope. In the absence of a derogation from the upcoming PFAS restriction for the manufacture and MRO of electrical and electronic equipment relying on PFAS used in industrial automation, several stakeholders in the supply chain would be affected. This includes PFAS manufacturers, PFAS processors, companies manufacturing PFAS-containing products (e.g., capacitors, lithium batteries, electronic circuits, semiconductors, seals, gaskets, etc.) as well as manufacturers of PFAS-dependent electrical and electronic equipment for industrial automation, such as the dossier submitter. Without feasible alternatives to PFAS, these companies would have to shut down their PFAS-dependent operations in the EEA. Moreover, in such a scenario, all downstream sectors using PFAS-dependent electrical and electronic equipment for industrial automation would not have access at least in part to spare components and maintenance services for such articles. Consequently, such affected industrial facilities located within the EEA would either shut down automatic production processes depending on electronic and electrical equipment or implement changes to enable a downgrade from automatic to manual manufacturing processes, if economically justifiable. Such a potential PFAS restriction scenario would therefore result in foregone profits, job losses, and additional one-off costs for dismantling and clean-up of facilities at the level of several stakeholders in the EEA, including manufacturers of PFAS-containing products, producers of PFAS-dependent articles for industrial automation, and downstream industrial sectors. Moreover, if businesses were to transition from automated to manual production processes, this would in turn lead to reduced operational productivity and safety, increased downtime risks, as well as reduced energy efficiency. This would in turn affect the competitiveness and market shares of the respective manufacturers, while there would be supply shortages of essential products on the EEA market (e.g., food products, medicines, semiconductors, energy, oil and gas, etc.) and potentially increased product prices for end customers. Furthermore, the non-availability of PFAS-containing products (e.g., semiconductors, lithium batteries, electronic circuits, etc.) could lead to severe implications for the digitalization and electrification efforts in the EEA, affecting European policies and strategies such as the Green Deal, the hydrogen strategy, and the digital transformation strategy, to mention only a few. Finally, the limited availability of MRO activities for PFAS-dependent articles in industrial automation would lead to premature retirement of assets, an increased volume of electronic waste, as well as higher resource consumption for waste treatment, resulting in additional carbon dioxide emissions in the EEA. |