**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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| 7880 | Date:  2023/09/19 16:23  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Switzerland  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  Request for exclusion of Fluoropolymers  Metrohm is a company with headquarter in Switzerland and subsidiaries in more than 50 countries, more than 20 thereof in the EU. We are a leading company with more than 3200 employees worldwide specialized in developing and manufacturing of analytical laboratory and testing equipment. We request that fluoropolymers which are considered to be polymers of low concern (PLC) according to the widely accepted OECD criteria [refer to shall be remove from the current PFAS restriction proposal. Analytical laboratory and testing equipment plays a critical role in many critical end sectors such as materials testing, pharmaceutics, food testing, environmental standards for air and water. Its equipment is necessary for the control and enforcement of legal regulations such as the REACH, Restriction of Hazardous Substances (RoHS) in electrical equipment, drinking water guidelines, the safety of toys, and various environmental laws, to name a few. If there were no derogations, the testing to support these standards would no longer be able to be carried out. This is due to the consideration that as yet no PFAS-free potential alternative has been qualified in laboratory equipment, and in many applications as yet an potential alternative with suitable characteristics has not been identified. As a manufacturer of such equipment, we are dependent on these fluoropolymers, e.g. PTFE, ETFE, FEP, PFA, FPM, PCTFE, PVDF etc. because of their excellent chemical and mechanical characteristics. Suitable alternative materials are currently not existing and are not expected soon. By including these polymers in the scope of the restriction proposal, we risk that laboratory equipment disappears from the market and essential applications for humans, environment and research are no longer available. There is the risk that the restriction may be followed by a global economic downturn as companies would not be longer able to carry out their core businesses. |
| Answer to specific info request 1:  Analytical laboratory and testing equipment plays a critical role in many critical end sectors such as materials testing, pharmaceutics, food testing, environmental standards for air and water. Its equipment is necessary for the control and enforcement of legal regulations such as the REACH, Restriction of Hazardous Substances (RoHS) in electrical equipment, drinking water guidelines, the safety of toys, and various environmental laws, to name a few. If there were no derogations, the testing to support these standards would no longer be able to be carried out. This is due to the consideration that as yet no PFAS-free potential alternative has been qualified in laboratory equipment, and in many applications as yet an potential alternative with suitable characteristics has not been identified. |
| Answer to specific info request 3:  We act as a downstream user and do not produce any PFAS substances ourselves, but we needed to use the fluoropolymers that are considered to be polymers of low concern (PLC) according to the widely accepted OECD criteria in our products. The potential environmental impacts of most products and components are likely to occur at the end of the life cycle of the devices as during production there are no emissions of volatile or low molecular PFAS. This is based on the consideration that PFAS polymers and other substances are thermally very stable and are not heated during equipment production or use, up to the temperature at which the polymers start to decay. Recycling is usually carried out only by licensed recyclers which is regulated. At the high process temperatures during incineration all PFAS should be completely destroyed so there would be negligible emissions at end of life. There are studies already published, which show that no harmful PFAS emissions occur with well-operated incinerators. Electrical and Electronic Equipment is regulated by the Waste Electrical and Electronic Equipment Directive (2012/19/EU), which recyclers are obliged to ensure that there are no emissions of polychlorinated biphenyls, furans and other toxic by-products and the conditions required to achieve this should also destroy PFAS. In the attachment we will share a published study which shows that no harmful PFAS emissions occur with well-operated incinerators: - Pilot-Scale Fluoropolymer Incineration Study-Preliminary report-June 2023.pdf Also attached are the following documents on the topic polymers of low concern (PLC): - OECD Risk Management 61 2021 terminology-per-and-polyfluoroalkyl-substances - Integr Envir Assess Manag - 2018 - Henry - A critical review of the application of polymer of low concern and regulatory |
| Answer to specific info request 4:  No significant effects are expected due to the existing EU legislation and the national regulations, e.g. in Germany by the Kreislaufwirtschaftsgesetz (KrWG). |
| Answer to specific info request 5:  We need about 15 tons of PFAS per year to manufacture our laboratory equipment. It should be noted that we do not manufacture any substances ourselves, but we act as a downstream user. e.g. turning and milling of plastics or use components in the assembly such as seals, O-rings, plastic housings, tubes etc. It should also be note that these are exclusively PFAS which are considered to be polymers of low concern (PLC) according to the widely accepted OECD. Emissions are almost without hesitation because only polymers are used which are polymers of low concern classified and the recycling is carried out by only qualified partners. |
| Answer to specific info request 6:  No statement can be made as no comparable alternative materials to the OECD PLC classified fluoropolymers are exist or will be available soon. Banning of these fluoropolymers would pose an incalculable risk. In the Attachment we will share our assessment of alternative materials required by our products, with the statement that currently no alternatives are available: - PFAS\_Alternative materials evaluation\_Metrohm |

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| 7881 | Date:  2023/09/19 16:23  Content:  Scope or restriction option analysis  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Römheld GmbH Friedrichshütte  Org. country:  Germany | General Comments:  - |
| Answer to specific info request 1:  Betrifft Dichtungen, die in Produkte eingebaut sind, die 76 % des Gesamtumsatzes betreffen. |
| Answer to specific info request 6:  PFAS-Dichtungen werden in unseren Produkten aufgrund von Druck-, Wärme- und Reibungsaufnahme benötigt. Eine adäquate und gleichzusetzende Alternative gibt es auf dem Markt nicht. Da 76 % unseres Umsatzes davon betroffen sind, ist die Existenz unseres Unternehmens bei der Umsetzung der PFAS-Richtlinien, speziell bezogen auf die von uns verwendeten Dichtungen, akut gefährdet. Dies würde somit den Fortbestand von 350 Mitarbeitern (gesamte Belegschaft) gefährden. Bei Verwendung von Dichtungen, die nicht mit PFAS-relevanten Stoffen versetzt sind, ist die Funktionalität unserer Produkte nicht oder nur sehr eingeschränkt gewährleistet. |

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| 7882 | Date:  2023/09/19 16:32  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:  Company  Org. name:  Siempelkamp Maschinen- und Anlagenbau GmbH  Org. country:  Germany  Attachment:    <redacted>  Privacy statement:  Confidential Business Information | General Comments:  Siempelkamp Maschinen- und Anlagenbau GmbH welcomes the opportunity to contribute to the public consultation initiated by the European Chemicals Agency regarding potential restriction of Per- and polyfluoroalkyl substances (PFASs) according to Regulation (EC) No. 1907/2006 (“REACH”).  Siempelkamp Maschinen- und Anlagenbau GmbH is an internationally active German family owned company. Sustainability and resource efficiency are the defining issues of our time. We bundle the answers to these challenges in our corporate claim “Intelligent engineering for future generations”. It stands for the energy with which we align our technologies with the future topics of digitalization and sustainability. “Engineering” refers to our core competence for which the name “Siempelkamp” has stood since 1883. As a technology supplier and systems provider for machinery and plant engineering, our core business is focused on the production of complete plants for the wood-based panel industry, as well as different types of press-systems. "Intelligent engineering" in summary illustrates our approach to continuously developing machines and technologies and thus shape the future of our industries. “For future generations” sums up our ambition to improve the world through our actions. Siempelkamp technologies are geared towards the careful use of resources and raw materials. We develop sustainable, durable products and future-oriented services. Our sustainability concept includes, for example, research and development in the areas of alternative raw materials and recycling or usage of our press-systems for future technologies e.g. in the area of light-weight components. Our portfolio is tailored to energy-efficient, sustainable production. In this way, we fulfill our corporate responsibility towards society.  We hereby provide additional information for a further use and refer to our previous consultation of September 4th, 2023.  With regard to the proposed restriction on the manufacture, placing on the market or use of PFASs we submit that for sealings under harsh conditions (Annex XV Restriction Proposal E.2.14. Lubricants) the proposed restriction does not adequately distinguish between the fields of application and service life time of the components/plants.  Request for exemption  We propose to approve the extended derogation of 12 years with a transition period of 18 months for sealings where the use takes place under harsh conditions or use is for safe functioning and safety of equipment. The extended derogation time will enable further research and development to identify alternatives. Additionally, we propose that the following wording should be incorporated into the REACH Annex XV Restriction Report regarding PFASs as Lubricants and Sealings:  Annex XV Restriction Report E.2.14 Lubricants under harsh conditions: • “In case of applications in a closed environment with defined human interactions an additional derogation period is possible if no alternatives have been established.” • “In case of applications for plants/components which service life time extends the derogation period an additional derogation period is possible if no alternatives have been established”  Annex XV Restriction Report E.2.XX Sealings under harsh conditions: • “In case of applications in a closed environment with defined human interactions an additional derogation period is possible if no alternatives have been established.” • “In case of applications for plants/components which service life time extends the derogation period an additional derogation period is possible if no alternatives have been established”  We propose that there is a missing use of PFAS. Both points from above apply here as well. The materials are used in a closed environment and extend the service life time. PFAS or PFAS-containing materials are widely used in sealings for a variety of applications. Regardless of the fact that there are various mentions within the Annex, hydraulics are completely ignored. Hydraulic systems always work with (high) pressure and the sealings have to resist various influences (e.g., increased temperature) under dynamic conditions. |
| Answer to specific info request 1:  This consultation for the Annex XV restriction report gives more specific information about the use of sealings under harsh conditions according Annex E.2.14. Table 9. Sealings which contain PFAS are used in a large number of Siempelkamp's products. The reasons for the use range from high temperatures to high pressures to a generally higher durability. To produce our sustainable wood-based materials (particleboards, MDF-boards, OSB-boards or even wood-fiber insulation boards), high-temperature sealings are used in our whole form- and pressing-line. Especially in our continuous press system (ContiRoll®), the operating temperature is around 270 °C. For finishing wood-based materials (particleboards, MDF-boards, plywood or multi-layer boards), produced by our ContiRoll® (see above) with coatings, our short-cycle coating systems are used. Special melamine-coated papers are applied under high pressure of up to 700 N/cm² and at a temperature of up to 220 °C. With our systems up to 250 cycles per hour (coatings per hour) under harsh conditions with high pressure and high temperatures are possible. Additionally, our systems can be used to produce wood-based insulations in various designs. These materials are widely used in the renovation or construction of buildings (also in accordance to the EU Green Deal). Our rubber-press systems are used e.g. in the production of conveyor belts or tread pattern for tires. Both products cannot be produced without our press systems. Conveyer belts replace trucks and tread pattern help to increase the resource efficiency. These press systems use high pressures with up to 320 bar while reaching temperatures above 100 °C in the area of the sealing. Fiberglass and carbon-fibre-reinforced polymers are materials for which our press systems can be used. Both materials are used for the construction of light-weight systems to increase their efficiency (e.g., planes, vehicles or else). Additionally, the service-time and durability of these materials is higher compared to alternatives e.g. made from metals. With pressures up to 350 bar and temperatures with constant 100 °C and peak 120 °C combined with a friction-reduction the requirements towards the sealings are very high. Since not every system can be improved using the above-mentioned materials, press systems for metal forming are still needed. Our systems can be used either in hot working or work hardening processes. With our variety of press systems our customers are able to produce chassis for planes, blades for turbines, parts for renewable energy systems, pipelines, and heat-exchanger. With pressures up to 350 bar and temperatures with constant 100 °C and peak 120 °C combined with a friction-reduction the requirements towards the sealings are very high. Some rare press systems generate pressures with up to 1,500 bar. Due to the high pressures and increased temperatures combined with e.g., short cycles the stresses on used seals are very high. The used high-temperature long-term synthetic sealings containing PFAS are used to reduce friction and prevent leakages. Currently, the high requirements cannot be fulfilled by other materials (please see DIN 3771-3, attached temperature-resistance-elastomers.pdf and Heinz K. Müller et al). They contain PFAS in a range of 40%-80% w/w. The sealings have a very limited weight reduction during use and most of the material (except of small amount of wear) is collected after maintenance. All of the sealings are made from solid material and contact is limited to trained staff during maintenance. Currently, there is no adequate PFAS-free alternative that would be reasonable for the plant operation of our customers. As stated by previous stakeholders in the Annex XV Restriction Report (E.2.1.14 Lubricants) there are no alternative sealings which could ensure the safe functioning, safety of equipment and a comparable service life time for the components under harsh conditions. Examples of used materials can be found in attached “Materials\_HydraulicSealings (German).pdf”, “productdatasheet double wiper (German).pdf” and “datasheet\_ptfe-sealing\_en.pdf”. As soon as PFAS-free alternatives become available that do not severely affect the customer in the operation and maintenance of the plant, we will switch to these alternatives. |
| Answer to specific info request 2:  To be able to operate our different systems accurately and safely and to ensure our customers a long service life, our customers need to change the sealings regularly according to our guidelines. The number of sealings depends on the system and only for our ContiRoll product a 5-year-interval for changing is defined (see attached document “ContiRoll\_-Cylinder-packing-change-interval.pdf”). For other systems the sealings are changed if a leakage occurs. In some cases, other sealings are renewed in this turnaround. As stated under no. 1, contact with people only occurs when changing the sealing. Since the sealings are solid, the handling is easy and uncontrolled emissions are expected to be extremely low. Apart from very minor wear and tear, all the material is replaced. By progressing wear of a sealing, the tightness decreases and leads to the need of replacement. It can be assumed that the amount of material wear out is far less than 1%. After usage the sealings are collected in a separate container and disposed as required by local regulations. To point this out: over 99% of the used material is collected without uncontrolled emissions. |
| Answer to specific info request 3:  In our respectively our customers’ cases, the use of PFAS substances is restricted to a closed environment that is only accessible to humans during maintenance. After usage the sealings are collected in a separate container and disposed as required by local regulations. Depending on local regulations, this prevents the per- and poly-fluorinated alkyl substances from accumulating or uncontrolled emissions. The effectiveness of incineration under normal operational conditions with respect to the destruction of PFAS and the prevention of emissions was evaluated in the following study: Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and poly-fluorinated alkyl substances (PFAS) in flue gas [Aleksandrov et al, 2019]. Additionally, the prevention of emission is regulated in the European industrial emission directive 2010/75/EU. |
| Answer to specific info request 5:  For over 200 ContiRoll® plants in operation worldwide, the amount of used sealings per system can be estimated to be around 65 kg. In total 13,000 kg sealing material is used. Every five years the sealings will be changed, resulting in an annual consumption of 2,600 kg. With a range of 40%-80% w/w the amount of PFAS is between 1,040 kg and 2,080 kg. For our other press systems, the variety and thus also the variety of sealings is much higher and more individual. Our press systems for composite materials, multi-stack, short cycle, rubber and metal press systems are usually in operation for 25-30 years. Individual systems can produce for up to 50 years. A total of between 250-300 press systems are currently in operation and each system requires between 5 – 25 kg of sealing materials each year (estimate). In total 1,250 – 7,500 kg of sealing material and 500 – 6000 kg of PFAS. The consumption is highly dependent on the use of the systems, as there are no defined intervals for a renewal of the sealings. The sealings are renewed when oil leaks. According to our major supplier, we and our customers purchase approx. 3,850 kg per year. This results in a share for PFAS of 1,540 – 3,080 kg per year for this supplier. Together with our other suppliers our purchase of PFAS is between 2,000 kg to 4,000 kg per year. All of these purchased materials are solid and there is limited wear of less than 1% w/w. |
| Answer to specific info request 6:  In Annex XV of the restriction report the use of PFAS-materials for large hydraulic-components is missing. In such systems the sealings have two functions. First and foremost is the sealing function under high pressure and partially high temperatures. Additionally, the sealing is not embedded in a static system as the cylinder is in motion. The friction reduction of the used materials is the second function. The requirements for such a material in a non-static environment are much greater compared to static sealings. Often the materials are tested under static conditions and the assignment to thermal stability does not reflect the real conditions. For static resistance properties, please refer to the attached diagrams "Diagram Temperature and Oil Resistance (German).PNG" and "Temperature Resistance-Elastomers.pdf". For our products there is currently no PFAS-free alternative. From our point of view, the available materials are not suitable for the intended use based on the values in the data sheets. The stress under field-conditions exceeds the potential strength of the used materials. An internal example in file “Press cylinder sealing system in short cycle press system.pdf” shows the need of PFAS containing sealings for our systems. The use of hydraulic systems in warm to hot conditions is not specific to our product. From our point of view, there seems to be a missing use to be considered in the ECHA assessments. |
| Answer to specific info request 8:  Since our plants are built to serve our customers for more than 30 years, we are proposing to approve the extended derogation of 12 years with a transition period of 18 months for sealings where the use takes place under harsh conditions or the use is for safe functioning and safety of equipment. Additionally, we propose that PFAS-containing sealings can continue to be used under harsh conditions if PFAS-free alternatives for harsh conditions do not enter the market within the extended transition period of 13.5 years, since the lifetime of our plants exceeds the derogation time. The sealings have to be replaced with exactly the same type. No other option like modification of the affected parts is possible. Thus, ensuring the operation of newly built plants or plants currently under construction until the end of its lifetime. Furthermore, due to insufficient thermal stability – also for temperatures below the material-specific temperature – the sealings would degenerate faster. Please see attached “Diagram temperature and oil resistance (German).PNG” and “temperature-resistance-elastomers.pdf” as well as our internal example “Press cylinder sealing system in short cycle press system.pdf”. Additionally, the risk of a failure increases in a significant way. A total failure of such a sealing lead to unplanned downtimes. Attached is an internal confidential example (“Press cylinder sealing system in short cycle press system.pdf”) showing this inadequate stability. Regardless of whether the temperature is within the range of currently available PFAS-free alternatives, the material is not able to withstand the conditions. Switching the material to a PFAS-containing material which is suitable for much higher temperatures, the massive degradation of the sealings stops. The customer confirmed our expectations with the corresponding feedback. This internal example proves, that the test conditions for the classification of materials do not reflect the real conditions in operation. As such press systems usually are designed and produced for the needs of our customers, there is no back-up and a loss of a system could result in life-threatening situations for our customers like an unplanned long-term interruption in their operations. The research activity regarding PFAS-free sealings for harsh conditions is part of our suppliers. We use the sealings in hydraulic systems and currently there is no way to redesign our systems without them. |

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| 7883 | Date:  2023/09/19 16:34  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  E.G.O. Elektro-Gerätebau GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Sector: Electronics, Household Industry, Uses: PTFE insulation sleeves of thermostats in harsh environmental condition (high temperatures) --> Use is not considered in restriction report. Therefore information are provided within point 3.6 and in the attachments |
| Answer to specific info request 6:  Description of use: PTFE insulation sleeve is used for electrical insulation of capillary tube of thermostats within baking oven to impose electrical short circuits due to wiring close to electrical components. Due to the high temperatures around the cavity and the tubular heating element (above 230°C), PTFE insulation sleeves are the only known material to fulfill properties and assure electrical safety. a) Approximately 4.587 km of cable is used per year. That refers to approx. 14t PTFE. b) Temperature resistances, flexibility, electrical insulation properties, lifetime c) PTFE insulation sleeves are used in various product variants (over 2.500 at E.G.O.). Furthermore are PTFE insulation sleeves in thermostats commonly used in industry for insulation purposes. d) Alternatives are not available e) No material that combines all properties of todays PTFE sleeve was found up to now. From technical point of view the sleeve is necessary inside the appliances to guarantee electrical safety, especially due to the fact, that baking ovens are hand assembled and it is not 100% safe, that the position of the capillary tube is always the same. Theoretically could a change in the routing in ovens affect the temperature requirements for insulation sleeve and other materials could be used. But due to huge variety of customers and application, each application would need to be assessed separately with unproportional effort. Also alternative materials have disadvantages in use. Glass fiber sleeves are not as flexible as PTFE sleeves and tend to fray at cutting edges, which leads to risk in electrical safety of ovens. Furthermore are costs of alternative sleeves and energy consumption in production significantly higher. If PFAS free sleeve would be found the transition period with lifecycle test, approbation for various product types (also at B2B customers), change of production and especially clearing the supply chain towards the final customer is probably minimum 3 years, which is why a transition period of 18months is utterly insufficient. If no PFAS free sleeve would be found also the transition period is way too short to change the wiring of complete product portfolio of over 2500 thermostats variants in even more customer applications. The PFAS free insulation and routing need to assure electrical safety. Cost are difficult to calculate. First of all implementation cost for change of material, lifetime test, approval (also for our B2B customers), change of applications and drawings, etc. are going into several 10.000€. Furthermore, additional cost for alternative insulation material will occur. f) see answers in e) g) Thermostats designed for temperature range above 230°C can't be sold anymore. Therefore a loss of big part of thermostat business could occur, which leads to decline in return and jobs. These thermostats are used in cheaper/entry market segment of baking oven. Alternatives are more expensive electronic controls. If baking oven with thermostats couldn't be sold anymore prices in the entry segment could rise by up to 50%. |

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| 7884 | Date:  2023/09/19 16:35  Content:  Environmental emissions  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  Spain  Company name confidential:  Yes | General Comments:  We are a Spanish company with more than 50 years in the market. We only work with technical plastics, PTFE (material with the presence of PFAS) being our greatest standard. Our knowledge of the world of plastics is extensive, but even more so is the knowledge of the applications of each and every one of our clients. We are aware that there are some PFAS that are aggressive for people and the environment and we are not against their regulation. But in the specific case of PFAS existing in everyday plastic materials for simple applications as well as those with high added value, we need to continue having some essential materials available. We are talking about materials such as PA, POM, PET or similar that in advanced versions contain additives with traces of PFAS. Or the omnipresent and essential world of fluorinated products with PTFE at the forefront. How can we omit the use of these materials that are so present and essential that they are impossible to replace in some applications if they are food materials, to be in contact with a food product or that are biocompatible materials in the human body? We do not understand that they are considered risk materials and their total elimination is considered if they are tested, proven and certified by the most prestigious organizations and even by the regulations of different countries. |

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| 7885 | Date:  2023/09/19 16:47  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7886 | Date:  2023/09/19 16:48  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Switzerland  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  Request for additional Derogation of Fluoropolymers for use in Laboratory Equipment for 13.5 years For details, please refer to section 6 «Missing uses. » |
| Answer to specific info request 1:  Please refer to Section 6 as our sector and sub-uses are not listed in Annex XV Table 9. |
| Answer to specific info request 6:  We are a company with headquarters in Switzerland and subsidiaries in more than50 countries, more than 20 thereof in the EU. We are a leading company with more than 3200 employees worldwide specialized in developing and manufacturing of analytical laboratory - and testing equipment and we miss completely our area of applications in the current restriction proposal (Annex XV Table 9 and Annex A Table A.1.) One of the listed intended derogations of the proposed restriction is diagnostic laboratory testing. It only deals with testing biological or medical samples. Equipment for analytical laboratory testing is a completely different application sector. Application fields are very widespread but mainly deal with analysis of chemical parameters in chemical industry, pharmaceutical industry, environmental monitoring and control, monitoring and control of drinking water and food and many others. As clarified with our legal department analytical laboratory equipment is not covered by diagnostic laboratory testing. Therefore, it is important to make a clear distinction between these application fields and to discuss analytical laboratory testing separately. Our products are not covered by the Medical Devices Regulations 2017/745 or In Vitro Diagnostics Regulations 2017/746. We would like to answer the other points: a.) As laboratory equipment manufacturer we only process, but do not manufacture raw materials with fluoropolymers. As a downstream user we do mechanical machining of plastics or use pre-fabricated components made from fluoropolymers in our assembly such as seals, O-rings, plastic housings etc. For note we use only fluoropolymers which are considered to polymer of low concern (PLC) according to the widely accepted OECD criteria, ,e.g. PTFE, ETFE, FEP, PFA , FPM, PCTFE, PVDF. We consume about 15 tons of fluoropolymers per year to manufacture our laboratory equipment. During mechanical processing no emissions of volatile and/or low molecular PFAS are generated. In general, all possible airborne releases are minimized by exhaust and ventilation systems. Air quality is regulated in national air pollution control ordinances. All types of mechanical processing material waste are recycled. Waste is regulated in national waste ordinances. Disposal of laboratory equipment as end-user product is subject to the WEEE Directive 2012/19/EU. As a consequence it is disposed of in hazardous waste. No other releases are known. Use of laboratory equipment: Fluoropolymers do not leach hazardous substances due to their chemical stability, no exposure known on and for the user side. b.) In analytical laboratory equipment and analytical laboratory testing fluoropolymers are used for a wide range of applications and purposes. Requirements for such equipment cover extreme ruggedness, the ability for reliable intense operation (24/7) over long time periods without servicing, expectations for a lifetime of more than 10 years under such extreme conditions. This goes hand in hand with extreme requirements to chemical properties of the used materials: The materials must show excellent chemical resistance against a wide range of chemically aggressive solutions, organic solvents and/or gases, the surfaces must be not-wetting and must not show adsorption effects for organic as well as inorganic chemicals. As a third point a high percentage of the used (mechanical) components must have excellent mechanical properties: High dimensional precision with very low tolerances (in the range of ±50 µm or below for accurate dispensing of very small solution volumes down to the sub-microliter range), long-term mechanical stability in a wide temperature range, excellent manufacturing properties (flow-injection molding or mechanical machining). c.) Analytical laboratory testing equipment is indispensable in a number of key industry sectors: Chemical & pharmaceutical industry, food testing, water & environmental analysis, energy supply, petroleum industry, etc. The global market size of laboratory instruments was estimated with 66.2 Bill. USD in 2020. With a growth rate of 8 – 15% depending on the regional sales and industry sector, a sales volume of more than 100 Bill. USD is expected for 2025. [refer to: Instrument Business Outlook 2021, March 2021 © Kalorama Information] The instrumentation is highly system relevant for analytics in human and public health & safety, starting from chemical safety over food & drinking water to reliable supply of pharmaceuticals. As an example: EU Directive 2018/725, also known as the “Toy Safety Directive”, stipulate strict limit values for hazardous substances in toys, e.g. the carcinogenic chromium (VI). These tight limits can be verified with our laboratory testing equipment. Also an important field in which analytical laboratory testing equipment is used, is the monitoring of the environment, e. g. air, water, soils. This also includes analytical equipment for testing PFAS, PFOA, PFOS. As another example, in the field of water & environmental analysis, one of the major issues is to ensure drinking water quality. With our laboratory testing equipment for ultra trace analysis, it is possible to determine contents of toxic heavy metals down to the lower ppt level. Dimensions become clearer if one considers that one ppt is the equivalent of a little cube of sugar dissolved in a reservoir containing 2.7 billion liters of water. Also other areas in the society are affected, such as energy supply which includes electrical power production and petroleum products. d.) For our products no alternative materials are available yet. Therefore a massive impact of the availability of laboratory testing equipment is expected. In case fluoropolymers have to be replaced by materials with lower performance there is a high likelihood that the maintenance frequency in our manufacturing processes and of our instrumentation in the field will increase and the manufacturing maintenance intervals and the service repair intervals in the field will decrease. Decreasing of chemical resistance can lead to reduced safety and reliability of the equipment, e.g. increased risk of leakage in the chemical application. There is a risk that this leads to human damage, decreasing precision or loss of data. A result of this are significantly increased costs of ownership for the instrument users but also for the internal manufacturing costs. If alternatives material do not have the same broad chemical resistance, it is possible that different versions of the products have to be developed, manufactured and maintained. This leads to higher development costs, manufacturing costs, increased prices and lower competitiveness. Additionally, as downstream user we are dependent on the availability of fluoropolymers in our whole supply chain. Numerous components that we source from 3rd party suppliers come with built-in subcomponents made from fluoropolymers. Examples are electronic and electric components, motors, valves, seals, connectors for gases or liquids and many more. e.) There is currently no alternative polymer in prospect for the fluoropolymers that are considered to be polymer of low concern (PLC) according to the widely accepted OECD criteria. As a downstream user we need to rely on plastic research and development for this. But in case that such an equivalent alternative material will be made available, the number of suppliers is expected to be limited (single source). Due to the fact that such materials with similar properties as fluoropolymers will be needed in high quantities by numerous industry sectors a shortage of the delivery amount and high lead times can be expected, going hand in hand with increased material price. With the publication of the PFAS dossier the supply chain of fluoropolymers has already become an issue. The situation may even get worse in case a ban of the substances is adopted. f.) Such a forecast is relatively difficult, because currently are no prospect of a fluoropolymer alternative is known or expected soon. For all the reasons mentioned above fluoropolymers are an integral key component of our products. Our products rely on this key material to provide proper functionality, safety, performance and quality to our customers. The various components made from selected material interact in a highly optimized and well-tested manner. Developing such high-tech equipment involves big working groups and typically takes 5 - 10 years. Simply exchanging a material in a complex instrumental setup by another material does not work. If materials have to be replaced it usually means a complete redesign of the complete assembly - which takes several years in a big working group again. The PFAS restriction will increase the development time for every product in our portfolio because experiences of 80 years in developing laboratory testing instruments cannot be used anymore. The fluoropolymers have been used for several decades, the behavior under temperature change, pressure, chemical load (pH changes, concentrated acids and bases, organic solvents) are well known and integrated in the developed setups. Such an impact would mean to hire additional staff to compensate for the massive re-design impact of our product portfolio. We have a tight development and innovation roadmap until 2030 which needs full involvement of our current number of employees in R&D. All these projects will have to be stopped. For the re-design our development staff must be duplicated. Another challenge is finding qualified staff for the development and manufacturing of our products, we need highly educated experts, who cannot be found in the European Union (EU) or Switzerland (CH) easily. In consequence we may have to shift development and manufacturing activities to countries outside the EU or CH, e.g. India. In the mid- and long-term perspective this will result in job losses in EU and CH. g.) No statement can currently be made on this point In the attachment we would like to share the following documents: 1. Our statement 2. Our assessment of alternative materials required by our products, with the statement that currently no alternatives are available. 3. A published study which shows that no harmful PFAS emissions occur with well-operated incinerators |
| Answer to specific info request 10:  Laboratory equipment is also used to analyze PFAS substances. Today Combustion Ion Chromatography (CIC) is one of the most promising analytical methods for PFAS analysis [see Attachments; Monitoring PFASs in water sources and Adsorbable organic fluorine (AOF) – a sum parameter for non-targeted screening of per- and polyfluorinated alkyl substances (PFASs) in waters]. This technique allows the quantification of the total organic fluoride content in gas, liquid and solid samples. As a non-target analysis technique CIC determines the sum of all PFAS substances independent from the chemical structure or availability of standard substances. Different standards are already referring to this method [refer to DIN norm (38409-59), upgrade to ISO in progress (TC 147/SC2), EPA method draft (EPA draft 1621)]. Without a derogation for laboratory equipment the analysis of PFAS substances will be impossible. |

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| 7887 | Date:  2023/09/19 16:54  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7888 | Date:  2023/09/19 16:55  Content:  Scope or restriction option analysis  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  E.G.O. Elektro-Gerätebau GmbH  Org. country:  Germany  Attachment:    <redacted>  Privacy statement:  Reason for confidentiality: Report shows research results for lubricants (including PFAS free alternatives) and gives insight in used/alternative materials and therefore affects intellectual property. This data is confidential and not designated for public view. | General Comments:  - |
| Answer to specific info request 1:  Sector: Lubricants/Electronics/Household Industry (Sub-)uses: Proposed derogation 5s - lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF Exemption 5s is currently necessary since nor alternatives are known yet. Lubricants/greases are used in energy regulators and thermostats (over 2000 different types). Energy regulators and thermostats are used in high temperature environments like hobs, ovens, heat pumps, boilers, fryers, sauna and many others. So far only lubricants based on PFAS could guarantee proper function of products (depending on the usage also safety relevant) over a long lifetime, minimum 10, sometimes 20 or more years due to its high thermal stability and excellent lubrication performance. This is especially relevant for safety cut-offs, these need to be reliable over 20 years or more. Short term substitution is not possible due to lack of alternatives, series qualification, life-time test and approval. Therefore, the proposed transition period of 13.5 years is needed to find substitutes. |
| Answer to specific info request 5:  Used tonnage approx. 1,5t per year Products are assembled in electrical and electronic equipment. This waste stream is regulated via WEEE (2012/19/EU). |

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| 7889 | Date:  2023/09/19 17:00  Content:  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Edwards vacuum  Org. country:  Czech Republic | General Comments:  Request for exemption. FFKM sealing parts are used for sealing most demanding application where aggressive chemicals are used  Reason: In above applications the reliability of sealing parts are critical. Other sealing materials like EPDM/NBR/HNBR/SIL are not compatible with process gases (the sealing material will be dissolved / or harden causing leaks).  From there perspective of reliability and safety FFKM are irreplaceable. |
| Answer to specific info request 1:  Vacuum pumps, scientific equipment, mass spectroscopy, electron microscopy, semicon ozon concentrators, exposure units, He recircullation, transport and many other applications |
| Answer to specific info request 2:  For fluoropolymer materials are used in the production of the product. We typically consider these are replaced as a precaution during major maintenance. At end-of-life, we suspect all materials are currently disposed of as part of regular waste. |
| Answer to specific info request 3:  PFAS (per- and polyfluoroalkyl substances) are widely used, long lasting chemicals, components of which break down very slowly over time. We aim to comply with any legislation which apply to our products such as REACH and ROHS. For this purpose, we retain lists of prohibited and restricted substances that are communicated to our suppliers. Although certain groups of PFAS substances have already been phased out (for example PFOA and PFOS), the majority of PFAS chemicals have not yet been regulated. |
| Answer to specific info request 6:  Missing sector = Scientific Equipment and Missing Sub-Use = Vacuum Pumps. |
| Answer to specific info request 7:  Request for exemption. FFKM sealing parts are used for sealing most demanding application where aggressive chemicals are used Reason: In above applications the reliability of sealing parts are critical. Other sealing materials like EPDM/NBR/HNBR/SIL are not compatible with process gases (the sealing material will be dissolved / or harden causing leaks). From there perspective of reliability and safety FFKM are irreplaceable. |

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| 7890 | Date:  2023/09/19 17:03  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7891 | Date:  2023/09/19 17:03  Content:  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Edwards vacuum  Org. country:  Czech Republic | General Comments:  Request for exemption. PTFE shaft seals are used for sealing most demanding application where aggressive chemicals are used. It provides were precise long lasting low friction seal.  Reason: In above applications the reliability of sealing parts are critical. Other sealing materials like EPDM/NBR/HNBR/SIL are not compatible with process gases (the sealing material will be dissolved / or harden causing leaks).  From there perspective of reliability and safety PTFE shaft seals are irreplaceable. |
| Answer to specific info request 1:  Vacuum pumps, scientific equipment, mass spectroscopy, electron microscopy, semicon ozon concentrators, exposure units, He recircullation, transport and many other applications |
| Answer to specific info request 2:  For fluoropolymer materials are used in the production of the product. We typically consider these are replaced as a precaution during major maintenance. At end-of-life, all materials as apart of shaft are currently disposed of as part of regular metallic waste for recycling. |
| Answer to specific info request 3:  PFAS (per- and polyfluoroalkyl substances) are widely used, long lasting chemicals, components of which break down very slowly over time. We aim to comply with any legislation which apply to our products such as REACH and ROHS. For this purpose, we retain lists of prohibited and restricted substances that are communicated to our suppliers. Although certain groups of PFAS substances have already been phased out (for example PFOA and PFOS), the majority of PFAS chemicals have not yet been regulated. |
| Answer to specific info request 6:  Missing sector = Scientific Equipment and Missing Sub-Use = Vacuum Pumps. |
| Answer to specific info request 7:  Request for exemption. PTFE shaft seals are used for sealing most demanding application where aggressive chemicals are used. It provides were precise long lasting low friction seal. Reason: In above applications the reliability of sealing parts are critical. Other sealing materials like EPDM/NBR/HNBR/SIL are not compatible with process gases (the sealing material will be dissolved / or harden causing leaks). From there perspective of reliability and safety PTFE shaft seals are irreplaceable. |

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| 7892 | Date:  2023/09/19 17:10  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7893 | Date:  2023/09/19 17:12  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7894 | Date:  2023/09/19 17:17  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7895 | Date:  2023/09/19 17:18  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  E.G.O. Elektro-Gerätebau GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Sector: Electronics/Lubricants, Household Industry, Uses: FKM sealing and PTFE based lubricant --> Use is not considered in restriction report. Therefore information are provided within point 3.6 and in the attachments |
| Answer to specific info request 6:  Description of use: FKM is used as sealing gasket in combination with a PTFE based lubricant in gas stoves with electronic user interface. The sealing gasket is used in valves to seal the system and prevent leakages. Within the gas stoves high operating temperatures arise during the cooking (above 250C°), therefore so far only FKM sealing gaskets and PTFE based lubricant were able to operate within these harsh condition and to fulfill regulatory standards for product safety. a) More than 100.000 gasket sealings and 10 kg lubricant b) Sealing gasket: Temperature resistances, durability, flexibility, lifetime Lubricant: Temperature resistances, durability c) Several customer(B2B) and end customers are affected. PFAS based sealings are commonly used in industry for comparable gas stoves. d) Alternatives are not available e) Currently no material known combines all properties of FKM sealing gasket, especially high temperatures (above 250°C). From technical point of view the sealing gasket is necessary to guarantee that no gas leaks out of the system and is therefore safety critical. Alternative materials not yet known. High temperature silicone sealing might be an option, but tests need to be performed. If a PFAS free sealing gasket would be identified the transition period with lifecycle test, approbation for various product types, change of production and especially clearing the supply chain towards the final customer is several years, which is why a transition period of 18months is utterly insufficient. Costs are difficult to calculate. First of all, implementation costs for change of material, lifetime test, approval, change of applications and drawings, etc. are going up to 50.000€. Furthermore, additional cost for alternative sealing gasket could occur. If no PFAS free sealing gasket is identified the transition period is even more critical since a complete redesign of the whole appliance is needed. Also costs of a complete redesign and new machinery are much higher, probably several 100.000€. f) see answers in e) g) We are confident to find an alternative solution, but not within 18months. If a PFAS restriction with transition period of 18 months would be introduced, these kind of valves can't be sold anymore. End user would have limitation in choice of gas cooking hobs and could switch to other hob technologies. That is connected with loss of return and threat of reduction in jobs. In many countries (e.g. Italy, Hungary, Romania) gas stoves have by far the biggest share of hobs used in households. Also production EU for other markets would be restricted with negative effect on locations based in Europe. |

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| 7896 | Date:  2023/09/19 17:24  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7897 | Date:  2023/09/19 17:25  Content:  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  Portugal  Company name confidential:  Yes | General Comments:  Our company is exclusively dedicated to the application of fluorpolymers, having found no suitable alternatives in the many years of practice. Our products provide many benefits to our customers, facilitating their production and without them many would face serious challenges in maintaining their production, facing many alterations to their processes with trial and error, resulting into a massive slow down or even halt of production. Our downstream of costumers is varied, we work with food, cork, shoes, molds, packaging, automotive, medicine, chemical, petrol, decorating and design and many other small and big industries, all of which need fluorpolymers in their process to be able to produce. Given this statement we would request an exemption seeing as there are no viable alternatives for so many important applications, and the consequences of banning fluorpolymers would be devastating not only for us but to all of our costumers. |
| Answer to specific info request 2:  The application process is very tightly controlled since the monitoring of emissions is in compliance with the current European legislation. The waste produced by our process is 100% dealt with by licensed and authorized entities for proper disposal. |
| Answer to specific info request 5:  We around 10.000 kg of fluorpolymers products per year, of which we do not have information on the percentage of PFAS. |
| Answer to specific info request 6:  If fluorpolymers are effectively banned there will be serious socio-economic repercussions in many sectors of the European industry since there in no replacement that is technically viable. |

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| 7898 | Date:  2023/09/19 17:25  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  E.G.O. Elektro-Gerätebau GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Sector: Electronics, Household Industry Uses: Cable insulation for ignitors in gas stoves --> Use is not considered in restriction report. Therefore information are provided within point 3.6 and in the attachments |
| Answer to specific info request 6:  Description of use: PTFE/PFA/MFA insulated cables are used in gas hobs for wiring of electrodes for ignition of gas. The PTFE wiring is used in all different kind of gas burners produced at E.G.O.. Wiring insulation for electrodes in gas hobs has high requirements on thermal stability (temperatures between 250-350°C) to assure electrical insulation and electrical safety. Wiring need to be compliant with approval criteria, e.g. UL for US market. Therefore PFAS based materials are used as cable insulation. a) Approximately 2mio pieces which are approx. 350kg PFAS. b) Thermal stability to assure electrical insulation at recurring high temperatures. c) All E.G.O. gas burners with electrodes are affected. PFAS based material is commonly used in industry for this application. d) Availability of Alternatives: Alternative wires are not yet available for this application. Possible alternative wires are being evaluated (see point e). e) The search for alternatives was started. A possible alternative has been identified but a deep analysis with lifecycle tests was not yet possible. Main challenges are to find wiring which has thermal stability and fulfills approval requirements. Even if the alternative cable would fulfill all requirements, a transition period of 18 months is not sufficient to perform lifetime tests, adapt technical documentation, get approval for products and clear the supply chain towards the final customers. Cost are difficult to calculate. First of all implementation cost for change of material, lifetime test, approval, change of applications and drawings, etc. are going up to 20.000€. With alternative cable negative economical and environmental effects come along. To the current knowledge only a multi-composite (fiberglass and mica) cable can fulfill technical/thermal requirements. On the one hand costs are inevitable higher. On the other hand is the resource use and energy consumption in production of those cables are also higher. Technical it is possible to operate gas stoves without electrical ignition, but it's a big loss of comfort for end-users and critical selling point. f) see answers in e) g) We are confident to find an alternative cable, but not within 18months. If a PFAS restriction with transition period of 18 months would be introduced, these gas burners/stoves can't be sold anymore. End user would have very limited choice of gas cooking hobs and would probably switch to other hob technologies. That is connected with big loss of return and threat of reduction in workforce. In many countries (e.g. Italy, Hungary, Romania) gas stoves have by far the biggest share of hobs used in households. |

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| 7899 | Date:  2023/09/19 17:29  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7900 | Date:  2023/09/19 17:31  Content:  Scope or restriction option analysis  Environmental emissions  Baseline  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:  Germany  Company name confidential:  Yes | General Comments:  Zu den ausführlichen Erklärungen, faktische Belege zu Emissionsfreiheit, Umweltmanagement etc. verweisen wir auf die Materialhersteller und -lieferanten (ILAG, Tetrachim, Daikin, Chemours usw.) Wir sind Lohnbeschichter und verarbeiten Fluorpolymere, welche bereits als gering bedenklich eingestuft sind. Eine Gruppierung von über 10.000 Stoffe unter einem Hut halten wir für absolut unsachlich und nicht umsetzbar. Mittlerweile werden die Fluorpolymere zu 99,9% Emissionsfrei hergestellt. Die Beschichtungen beispielsweise in der Pfanne sind ebenfalls unbedenklich, da diese einfach vom menschlichen Körper wieder ausgeschieden werden. Ein komplettes Verbot inkl. den Fluopolymeren (inkl. Verbot für Einfuhr und Verwendung) hinterlässt eine industrielle Wüste in ganz Europa. Fluorpolymere sind in der Medizintechnik alternativlos. Ebenso in de Chiptechnik, für 5G, in der Batterieherstellung für die E-Mobilität und auch bei Wärmepumpen sind diese Stoffe unersetzlich. Die Green Ziele, das Abstoßen der Verbrennermotoren und die Durchsetzung der Wärmepumpen wären nicht durchführbar. Es ist zwingend erforderlich weitere Gruppierungen vorzunehmen, da nicht alle Stoffe gleich zusetzen sind. Die REACH beurteilt normalerweise jeden Stoff separat und die Fluorpolymere sind als unbedenklich eingestuft. Weshalb man Sie nun mit 10.000 anderen Stoffen (teils gefährlichen Stoffen) zusammenführen will, entzieht sich dem normalen Menschenverstand. Sollte ein komplettes Verbot kommen müssten wir 14 Mitarbeiter entlassen und könnten unsere Kunden nicht mehr bedienen. |
| Answer to specific info request 1:  Sector as a whole, Lebensmittelindustrie, Medizintechnik, Automobilbranche, Textil- und Papierbranche, Analgen- und Maschinenbau, Reinraumanwednungen, Chemieindustrie, Chipindustrie, |

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| 7901 | Date:  2023/09/19 17:32  Content:  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Hazard or exposure The seals we use are permanently installed in enclosures. An uncontrolled release is therefore impossible. Environmental emissions When the seals are replaced, they can be safely removed and fed into a disposal cycle. Contamination of the environment through abrasion is largely excluded. Baseline We use both, static and dynamic seals to seal our gearboxes. For this purpose, we exclusively use seals made of FKM (Viton). Benefits and Alternatives Due to the process, the seals must be temperature resistant up to 160°C. The shaft seals must haHazard or exposure The seals we use are permanently installed in enclosures. An uncontrolled release is therefore impossible. Environmental emissions When the seals are replaced, they can be safely removed and fed into a disposal cycle. Contamination of the environment through abrasion is largely excluded. Baseline We use both, static and dynamic seals to seal our gearboxes. For this purpose, we exclusively use seals made of FKM (Viton). Benefits and Alternatives Due to the process, the seals must be temperature resistant up to 160°C. The shaft seals must have a low frictional resistance in order to produce as little abrasion as possible and they must be resistant to a wide range of operating materials (various oils, cooling lubricants, additives, etc.). There is a corresponding alternative material available that has these properties. Request for exemption Behringer-Eisele GmbH applies for an unlimited exemption of the static and dynamic seals made of FKM (Viton) used by us, as our requirements regarding function and resistance must be fulfilled, alternatives are not available and contamination of the environment is largely excluded.ve a low frictional resistance in order to produce as little abrasion as possible and they must be resistant to a wide range of operating materials (various oils, cooling lubricants, additives, etc.). There is a corresponding alternative material available that has these properties. |

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| 7902 | Date:  2023/09/19 17:35  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7903 | Date:  2023/09/19 17:36  Content:  Scope or restriction option analysis  Information on alternatives  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  <redacted>  Org. country:  Netherlands  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Information provided includes commercial- and competition-sensitive information, the usage of which is typically restricted to INTERNAL USE and the disclosure of which may harm our commercial interests. We have, and will continue to, spent considerable time, money and effort in associated R&D and IPR creation and cannot afford jeopardizing the novelty of the associated results. | General Comments:  The summary of the specific materials we ask for and exception due to the unavailability of an alternative within 20-30 years are all specific chlorine production specific PFAS containing parts such as; 1) Ion exchange membrane, these membranes can maintain performance under harsh conditions 2) Hoses and tubes, they need to be flexible and chemical resistant, and in the harsh environment of ion exchange membrane method for chlor-alkali electrolysis 3) Cell gaskets, these need to be flexible and chemical resistant, and in the harsh environment of ion exchange membrane method for chlor-alkali electrolysis 4) Hose gaskets, these need to be flexible and chemical resistant, and in the harsh environment of ion exchange membrane method for chlor-alkali electrolysis  See attached document for our full explanation on this general comment |
| Answer to specific info request 2:  See attached document. |
| Answer to specific info request 3:  See attached document. |
| Answer to specific info request 5:  End-of-life membranes will be less than 10 tons in 30 years and is out side the scope of Table 1. Summary of main restriction option (RO) assessed, their emission reduction potential, cost and cost effectiveness. |
| Answer to specific info request 6:  See attached document. |
| Answer to specific info request 7:  See attached document, chapter 4 "Pathway for the potential replacement of fluoropolymers" |

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| 7904 | Date:  2023/09/19 17:39  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7905 | Date:  2023/09/19 17:41  Content:  Scope or restriction option analysis  Environmental emissions  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Siemens Energy Global GmbH & Co. KG // Business Area: Compression  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  Protection of commercial interests / Details of Portfolio information / including intellectual property | General Comments:  1. Scope or restriction option analysis: Compression products and technologies are an essential element of a wide range of applications of industrial gases compression (including in renewable energy applications). These applications have however not been appropriately considered by the restriction proposal. The compression business is 100% dependent on the supplier’s ability to provide alternative material and product development. The socioeconomic impact (concerns SEAC) is tremendous, because the PFAS ban effects 90 % of Siemens Energy Compression business and slows down the energy transition if no derogation time in addition to the 18 months is granted. The compression technology includes solutions for essential industrial applications as well as decarbonization technologies like Hydrogen-(H2)-compression, Oxygen-(O2)- compression. The specific applications are dependent on PFAS containing materials, mainly fluoropolymers and fluoroelastomers. A transition time of 18 months as proposed in the restriction proposal is insufficient and stops the business for new and service projects. That impact would last until alternatives are available. According to our suppliers, alternatives are not available, the transition time cannot be estimated. Customer machines in service today would need to be taken out of service due to the lack of alternatives for spare parts, safety alerts must be announced worldwide. We therefore kindly ask to reconsider the ban proposal regarding compressors of multiple applications and the service of these applications. A derogation time of 18 months + 12 years (RO2), the maximum currently possible is therefore needed. Even a selective exception should be considered for specific application ranges (e.g. high and low temperature compressors, compressors for aggressive / oxidizing/ reducing atmosphere).  2. Environmental emissions: SE CP Industrial compressors do not emit PFAS into the environment during operation. Currently there is no recollection and recycling process established. It is likely that components will be made from recycled materials soon, which reduces the material consumption and production born emissions. Recycling process steps to recover material have already been introduced in general and the waste- management-process will be detailed by components’ suppliers/manufacturers. In case of this option fluoropolymer materials in components like sealing cords, cables, etc. will be recollected and either recycled or incinerated to mineralization stage after the end-of-life. In these cases, there is no release of PFAS after end-of-life. The waste-management-process will be defined together with customers, components’ suppliers, and manufacturers. In a general context it is of importance to consider and to recognize, that with a waste-management-process on top of that, compressor applications with large installed fleets of compressors of all kinds do not represent a significant source for PFAS related environmental pollution.  3. Information on alternatives: Currently, fluoropolymer suppliers state that there are no materials with comparable properties and application ranges available or alternative materials are not comprehensively suitable. Developments are ongoing and alternatives are not available until 2024 or later. The properties of these future alternatives and compliance with key standards, qualification and certification requirements are unclear at this stage. Important for the context is to recognize timelines. Fluoropolymers have been known in industry for many decades in commercial products. It has taken several decades to establish them in all the necessary technical aspects on a reasonable cost basis. Alternative materials are at least two orders of magnitude more expensive than standard polymers (if applicable at all). Alternatives that may be known today need to be tested at their Technology Readiness Level (TRL) and there are at least 3-4 years left for implementation. The potentially increasing pricing will be most likely a minor issue but thermal and chemical stability and lifetime requirements for an industrial product cannot be met at current. More time will be needed to qualify the polymer material maturity regarding sufficiently chemical stability, for all the different types of compressors, medias, and temperature ranges (-196°C to above 350°C) and compressor design sizes. The material would have to be available in large quantities, and furthermore the production processes on the supplier’s side must be developed and implemented correspondingly. Such conversions take at least 6 to more than 10 years before they can become effective. After stable production, a qualification process must be carried out. The transition period proposed in the ban proposal is also unrealistic even if an alternative would be available in the foreseeable future. The customized design and subsequent production time of industrial compressors is at least 12-18 months per order. This does not consider certifications or acceptances by customers in the international compressor business.  4. Other socio-economic analysis (SEA) issues: The impact on PFAS emission reduction from the energy sector is marginal with an estimated amount of 55t/a out of 74000t/a PFAS emissions in total. The current proposal of the PFAS ANNEX XV report would however have a major impact on essential parts of the society. With regards to service, repair and maintenance for products already placed on the market are heavily impacted as they must be compliant with customer requirements of end-of-lifetime guarantee and considering the EU green deal to produce longer lasting products that can be repaired, recycled, and re- used. With the current approach of banning PFAS (fluoropolymers) with only 18 months after EiF, products already on the market cannot be maintained, which is in complete contrast to the EU Green Deal approach.  There will also be a significant impact in other industries such as the downstream processes of the chemical industry, which we supply with all kinds of compressors or expanders. PFAS-containing seals are essential for all related applications. Compressors could not operate without these PFAS-containing seals, as the material is relevant to safe operation and performance and is also required by standards. Many other examples of professional industrial applications of the material could be cited. What they all have in common is that the financial impact on the entire European economy seems small at first glance, but this is misleading. Without the central function of components containing PFAS, compressors and their industrial equipment cannot operate. This leads to an immeasurably higher negative European economic outcome, as 90% of the compressor business is affected.  5. Transitional period: To justify a qualified request for changes on the transitional period/deferred entry into force a fundamental aspect is missing. For several industrial applications no qualified alternative material is available yet. The evidence is statured itself by “non-availability of alternatives”, similar stated for specific applications with fluoropolymer sealings like for: • petroleum and mining sectors and that the substitution potential is uncertain. • Low temperature refrigeration below -50°C, • Laboratory test and measurement equipment, • Refrigerated centrifuges, where rotor crash failure would result in a hazard from both a high-pressure system (carbon dioxide) or flammable hydrocarbons. If alternatives would be available, the qualification process would have to start from this point and it would take several years, depending on the Siemens Energy product portfolio. Industrial compressor applications demand a lifetime of multiple years which requires pre-qualification time in test rigs and test applications. The implementation into the production lines and scale-up of the production capacity of the alternatives by our suppliers will add time on top. A transition time of 6 to 10 years is common for such drastic adaptions to an industrial product.  6. Request for exemption: Products in the market and in use should be exempt to allow service. An exemption must be granted for products already on the market that are still being maintained and repaired. It should apply until the technical lifetime of the product is reached or reliable alternatives are available. Otherwise, confidence in our company as reliable supplier will be destroyed as the customer will suffer from significant lost investment because the product will become unusable. The insignificance of the PFAS substance quantities used (e.g. compared to the non-energy industry market) and thus the negligible emission potential for the environment on the one hand, and the delayed energy transition and recognizable negative impacts on industrial processes on the other hand, qualify industrial compression technologies for reconsideration and exemption. |
| Answer to specific info request 1:  See confidential attachment. |
| Answer to specific info request 2:  See confidential attachment. |
| Answer to specific info request 3:  See confidential attachment. |
| Answer to specific info request 4:  See confidential attachment. |
| Answer to specific info request 5:  See confidential attachment. |
| Answer to specific info request 6:  See confidential attachment. |
| Answer to specific info request 7:  See confidential attachment. |

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| 7906 | Date:  2023/09/19 17:43  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7907 | Date:  2023/09/19 17:46  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7908 | Date:  2023/09/19 17:47  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 a PFASs within packaging components, including for 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 detail 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. Lastly, it shows the commercial relationship between the company and its suppliers, that also constitutes sensitive information. 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 included in Section V. |
| Answer to specific info request 1:  Please see confidential attachment included in Section V. |
| Answer to specific info request 2:  Please see confidential attachment included in Section V. |
| Answer to specific info request 6:  Please see confidential attachment included in Section V. |
| Answer to specific info request 7:  Please see confidential attachment included in Section V. |
| Answer to specific info request 8:  Please see confidential attachment included in Section V. |

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| 7909 | Date:  2023/09/19 17:52  Content:  Request for exemption  Type:  Individual  Country:  China  Attachment: | General Comments:  - |

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| 7910 | Date:  2023/09/19 18:03  Content:  Information on alternatives  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Netherlands  Company name confidential:  Yes | General Comments:  We are a coating company who apply fluoropolymer coatings on parts for different industries. |
| Answer to specific info request 1:  The fluoropolymer coatings we use give solutions to all kind of industries, for example: medical, food, packaging, aerospace, semiconductor, textile, automotive and chemical industry. |
| Answer to specific info request 2:  Fluoropolymers are not a risk to human health or environment. They do not dissolve in or contaminate water and cannot enter of accumulate in a persons bloodstream. Fluoropolymers meet the OECD's criteria for polymers of low concern, they do not present significant toxicity concerns and cannot degrade into other PFAS. They are not mobile, bio accumulative, or toxic. Thus they should not fall under the proposed restrictions' scope, as fluoropolymers safety is guaranteed over their entire lifecycles. |
| Answer to specific info request 3:  The fluoropolymers can be destroyed by incineration. When deposited to a landfill the fluoropolymers are inert, non toxic and non-mobile. |
| Answer to specific info request 5:  Since the emissions of PFAS from fluoropolymers is very low, thus fluoropolymers should not fall under the scope of the proposed restriction, they should be fully exempt. |
| Answer to specific info request 6:  We are only a small applicator firm, we work with 15 employees. We do have a lot of satisfied customers. There are no equivalent alternatives to our fluoropolymer coatings. The fluoropolymer coatings have unique and vital combination of properties that allow them to withstand the most challenging and high stress conditions. Including fire, weather, temperature, chemical resistance and non-wetting, non sticking properties and high performance dielectric properties. For most of our coatings and uses are no alternatives. While some chemistries might offer a similar performance to fluoropolymers for a particular parameter or property, it is the unique combination of properties that sets fluoropolymers apart and makes them vital to the sectors and industries they serve. Their unique combination of properties makes them durable, efficient, reliable, versatile, and ultimately fundamental to the products they enable. As it will take years or decades to develop alternatives – if possible – a phase-out of fluoropolymers will result in a significant gap in capabilities for innovation, products, and industries. |
| Answer to specific info request 7:  We apply coatings for the medical industry, even with a derogation, it is almost impossible to find an alternative. All the years of development are thrown away. There will be no investments anymore, this will destroy the market. We really need an exemption. There are lots of other substances were we can get easier and more environmental profit. Also for use in industrial food industry we do need the fluoropolymers coatings. There are no better alternatives, the alternatives even have a bigger environmental and health impact. If we totally ban the fluoropolymers the European industry will be lost. If we also can not import these polymers, the European industry will be totally lost. |
| Answer to specific info request 8:  We are afraid that Europe will lose a lot of industry. Especially industries for the green deal; automotive electrical cars and all development of hydrogen energy. Chip industry which supply lots of knowledge (car industry, weapon development), employees and turn over in Europe. When this happens it will be to late to start over again. We will have to import everything from places were environment is not looked after at all. |
| Answer to specific info request 9:  Fluoropolymers really do need to a time unlimited derogation!! They are a specific class of PFAS with a unique and vital combination of properties in designated applications now and in the future with responsible manufacturing of fluoropolymers and responsible life cycle management. A broad ban on PFAS would significantly impact European business and industries that rely on these critical substances. They are irreplaceable! |
| Answer to specific info request 10:  We support industry-wide government regulation that is science-based, targeted, consistent, and benefits society and the environment. A one-size-fits-all regulation is not the right approach. |

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| 7911 | Date:  2023/09/19 18:10  Content:  Scope or restriction option analysis  Hazard or exposure  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:  Japan  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  This information has our commercial interests, including intellectual property, would be undermined. | General Comments:  We manufacture a large number of various types of plastic bags and supply them to the world, mainly in Japan. Fluoropolymer is indispensable for manufacturing plastic bags. We support the two statements made by JFIA and FCJ on the issues of proposed restriction, as per attached in Section IV. |
| Answer to specific info request 1:  "Plastic packaging" in the food contact materials and packaging sector (Annex E.2.3.) or "Other niche applications" (Table A.1. in the Annex A "Manufacture and uses") \*Here, we comment on cases where PFAS is not directly added to plastic packaging, but fluoropolymer among PFAS is indirectly used as industrial secondary materials. |
| Answer to specific info request 6:  If it is considered as "other niche applications", please see attached confidential file in the Section V. |
| Answer to specific info request 8:  If it is considered as "plastic packaging", please see attached confidential file in the Section V. |

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| 7912 | Date:  2023/09/19 18:19  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  EFORT European Federation of National Associations of Orthopaedics and Traumatology  Org. country:  Switzerland  Attachment: | General Comments:  • Endoscopes: PFAS are used to create the seal between the metal scopes and cannulas in endoscopes (e.g. minimal invasive arthroscopic surgery, abdominal surgery). This tight PFAS connection is essential to have maintain a sterile working environment. Concerning arthroscopic knee surgery alone, about 8 million procedures are performed annually in the EU, not taking into account the other joints, or the whole field of general and gynaecological surgery using these devices. • Medical devices in body contact need to be biocompatible which fluoropolymers prove to be. • Electrosurgical medical devices need high disruptive strength, high creep resistance and high electrical resistance currently provided by PFAS. |

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| 7913 | Date:  2023/09/19 18:23  Content:  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SIEMENS AG  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  The uploaded confidential information contains among others product information, further details and business data. These information relate to commercial interests as well as intellectual property. The protection of those interests would be undermined. | General Comments:  PFAS are widely prevalent in the industry and may be contained in or used to produce a. o. semiconductors, cables, connectors, batteries, electric drives, heat pumps, sensors, medical technologies. That’s because of their high thermal and chemical resistance, specific dielectric properties and the fact that they have a very low surface tension and are thus water and oil repellent, as well as abrasion and wear resistant at the same time. Siemens does not manufacture substances itself from the PFAS group. But especially electronic articles consist of many components and a restriction impacts each individual sub-article in every component. We elaborate on details further below and in the information provided in the attachment. |
| Answer to specific info request 1:  Our comment applies among others to the following sectors and uses: Air conditioning and heat pumps Mobile Air Conditioning (MAC) Transport Solvents Fire suppressants Insulating gas in electrical equipment Electronics Energy sector Lubricants |
| Answer to specific info request 5:  Please find the respective comments in the uploaded attachment. |
| Answer to specific info request 6:  Please find the respective comments in the uploaded attachment. |
| Answer to specific info request 7:  Please find the respective comments in the uploaded attachment. |

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| 7914 | Date:  2023/09/19 18:30  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Gigahertz Optik GmbH  Org. country:  Germany  Attachment: | General Comments:  Gigahertz-Optik uses PTFE for key functions of their high-end light measurement devices with ISO 17025 accredited calibration based on their own calibration laboratory. Beside of use of PTFE for measurement devices and systems Gigahertz-Optik manufactures longtime stable und precise calibration standards for light measurements. PTFE is in this case just a small part of the whole measurement systems and only used in small amounts but cannot be replaced due its technologi-cal unique features. Several studies showed the superb UV stability, lowest aging under light conditions and mechanical stability. No material was close to these specifications. Gigahertz-Optik also provides OEM-components made of optical PTFE for photonic and optical applica-tions like integrating spheres (Ulbricht spheres), laser resonators and light manipulating devices and others for various industrial and scientific applications. The use of PTFE for products and applications of Gigahertz-Optik is not related to any hazardous sub-stance and no degradation of long time preventing environmental pollution. PTFE is a polymer of low concern (PLC) in terms of its potential environmental and human health impact. In addition, the lifetime of the mentioned products can be easily reach 25 years and is not a wear tear product. These are technically irreplaceable core elements. Environmental emissions: During PTFE processing, emissions of PFAS-of-concern due to heating of the PTFE in the sintering process does not occur. More than 95% of the generated waste of the production process is reused or recycled! Just a very small portion is too much contaminated (e.g. dirt) and leaves the factory for incineration. It is shown in scien-tific studies that municipal incineration of fluoropolymers using best available technologies is not a signif-icant source of PFAS and should be considered an acceptable form of waste treatment. The contribution of PTFE to microplastics is estimated very low due to persistence. PTFE has a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS. The PTFE used in photonic applications can be also refurbished by a certain amount. Any restriction of PTFE for these applications at Gigahertz-Optik cannot be compensated with existing materials at same function and performance level. Therefore, competitors in U.S.A., India, China and other countries will take away from Europe this high-tech business in case of no exemptions of re-strictions causing dramatic economic impact. Request for exemption: Fluoropolymers should be exempted from any regulatory action under the REACH restriction for all applications in the branch of Photonics, which is an enabling technology for new high-tech products to improve life today and in future. Also, other exemptions in the photonics showed that it is often not possible to replace certain materials due to the very special optical needs in light transmission and aging. Exemption for PTFE used in high tech products and production aids for scientific and industrial applications!! |
| Answer to specific info request 1:  The branch Photonics at all and sub-categories are not listed in the sectors of ECHA. |
| Answer to specific info request 2:  More than 95% of the generated waste of the production process is reused or recycled! Just a very small portion is too much contaminated (e.g. dirt) and leaves the factory for incineration. It is shown in scientific studies that municipal incineration of fluoropolymers using best available technologies is not a signif-icant source of PFAS and should be considered an acceptable form of waste treatment. The contribution of PTFE to microplastics is estimated very low due to persistence. PTFE has a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS. The PTFE used in photonic applications can be also refurbished by a certain amount. |
| Answer to specific info request 3:  During PTFE processing, emissions of PFAS-of-concern due to heating of the PTFE in the sintering process does not occur. More than 95% of the generated waste of the production process is reused or recycled! Just a very small portion is too much contaminated (e.g. dirt) and leaves the factory for incineration. This is described in detail in the contribution of Berghof Fluoroplastic Technology (Contribution number: 5929; date/time: 2023/06/28 15:52; document: part 25, page 20) It is shown in scientific studies that municipal incineration of fluoropolymers using best available tech-nologies is not a significant source of PFAS and should be considered an acceptable form of waste treatment [Aleksandrov 2019]. The contribution of PTFE to microplastics is estimated to be very low due to persistence. PTFE has a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS [Yuan 2022]. The PTFE used in photonic applications can be also refurbished by a certain amount. The handling of optical PTFE as polymer of low concern (PLC) used in industry and research only can be safely managed [Henry 2018]. [Aleksandrov 2019] Aleksandrov et al., Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, Chemosphere 226, 2019, 898-906 (https://doi.org/10.1016/j.chemosphere.2019.03.191) [Yuan 2022] Yuan et al., Ranking of potential hazards from microplastics polymers in the marine environment, J. Hazard. Mater. 429, 2022, 1–19 (https://doi.org/10.1016/j.jhazmat.2022.128399) [Henry 2018] Henry et al., a critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Integr. Environ. Assess. Manag. 14(3), 2018, 316-334 (https://doi.org/10.1002/ieam.4035) |
| Answer to specific info request 4:  More than 95% of the generated waste of the production process is reused or recycled in the factory. Just a very small portion is too much contaminated (e.g. dirt) and leaves the factory for incineration. It is shown in scientific studies that municipal incineration of fluoropolymers using best available technologies is not a significant source of PFAS and should be considered an acceptable form of waste treatment. The contribution of PTFE to microplastics is estimated very low due to persistence. PTFE has a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS. |
| Answer to specific info request 5:  Very low tonnage and zero emissions are expected since optical PTFE is a polymer of low concern (PLC) in terms of its potential environmental and human health impact. |
| Answer to specific info request 6:  PTFE for optical applications and photonic industry and research: Optical industry, light measurement technology, Laser industry, LED manufacturing, LED-lighting design, environmental measurements (UV-radiation, Ozone), spectral measurements, LiDAR, Photonics (f.i. dis-plays, digital cameras), optical communications) Applications: Optical properties of PTFE applied in • Reflection standards • Interior of Ulbricht integrating spheres • Diffuse reflectors • Projection screens • Display backdrops • Reflectors for highly intensive radiation sources and lasers • Photonic devices and systems a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use. The annual tonnage is very low and limited to industrial and scientific applications. b. The key functionalities provided by PFAS for the relevant use. - Optical properties (reflection and scatter) from UV to IR range of light - Ultra stable optical properties over a very long time due to persistence of optical PTFE - Soft optical PTFE allow very complex and advanced mechanical shapes and versatile designs. c. The number of companies in the sector estimated to be affected by the restriction. Approx. 1.000 companies (EU) in the field of Photonics of might be affected. d. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected. Recently there is no equivalent material alternative available. e. For cases in which alternatives are not yet available, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or fi-nancial 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. There has been no alternative with equivalent set of properties found so far and also no money gained to finance required basic research. The results and success of the required basic research are unpredictable. f. For cases in which substitution is technically and economically feasible but more time is required to substitute: i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs); n.a. ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals); n.a. iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected addi-tional energy consumption); n.a. iv. information on the benefits for alternative providers. n.a. g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employ-ment numbers for the sector. The total loss will be in range of 10+ Billion Euro (Europe) related to all affected applications de-rived from EU Photonics Market Data and Industry Report 2020 (photonics21, tematys). Beside of lost business the knowledge and performance level in Photonics Europe will decrease against other countries outside Europe without ban of PFAS. |
| Answer to specific info request 7:  Beside of loss of business, jobs, taxes and know-how in case of ban of optical PTFE the high-tech industry Photonics as an enabling technology (i.e. Photonics) impacts on a broad range of applications. This branch and other related sectors will be tremendously weakened. There is no benefit if banned. |
| Answer to specific info request 8:  The global annual revenues for photonics-enabled products exceeded $2.1 trillion in 2021 (SPIE Industry Report 2022). Therefore, the impact of ban of optical PTFE is difficult to determine but definitely huge. |