**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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| 4081 | Date:  2023/05/11 17:22  Content:  Request for exemption  Type:  Individual  Country:  Japan | General Comments:  We want full exemption for fluoro elastomers . We need this fullexemption for fluoroelastomer |
| Answer to specific info request 1:  Fluoro elastomers are widely used for automotive ( engine cylinder block gasket, fuel hose , EV battery separator sheet , gasoline gas return hose ) , semiconductior manufacturing machine( gasket and sealing packing) |
| Answer to specific info request 5:  We run fluoroelastomer compounding factory. We use about 100tons fluoroelastomer polymer per year in last 20 years . We have no fact that Fluoroelastomer polymer gives human body influence ,such as cancer generation on our factory operators. |
| Answer to specific info request 6:  If Fluoroelastomers are restricted for manuafacturing , for use , car cannot be manufactured. Semicoductor cannot be made, aerospace rocket , missile cannot be made , millitary vehicle, airplane cannot be made, which give serious impact to national security . |
| Answer to specific info request 7:  There is no alternative chemical product which has equal technical perperty of fluoroelastomers. |

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| 4082 | Date:  2023/05/11 17:29  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  We supply confidential data in regard to Regulation (EC) No 1049/2001 Article 4(2) “commercial interests of a natural or legal person, including intellectual property”. | General Comments:  As an industrial supplier of plastic components, used in chemically aggressive and corrosive applications in different industry sectors (e. g. chemical, pharmaceutical, environmental, mining, metallurgy), we are pleased to share our knowledge about applications and risks of PFAS and their potential restriction.  We certainly support actions for enhanced human health and environment protection. The approach of a full ban of PFAS with or without different derogation options (RO2 or RO1 of the restriction report) though contains both harmful and risky substances (e.g., PFOA, PFOS) as well as substances of low concern, like the high molecular fluoropolymers. There are ongoing efforts of the industry to develop feasible recycling processes (https://www.science.org/doi/10.1126/science.abm8868) and companies like Gujarat Fluorochemicals work on substituting PFAS (https://www.gfl.co.in/assets/pdf/GFL%20Announcement%2030.11.22\_new.pdf). These advances are likely to be implemented in the near future. Though right now the properties of fluoropolymers in terms of chemical resistance are second to none. Although there are non-fluoropolymeric materials with very good technical and thermal-mechanical properties (e.g., PEEK, metals), these often do not offer the required chemical resistance and would not be economically justifiable for cost reasons. Therefore, fluoropolymers are indispensable (s. section III – 6). Regarding economical aspects, the prices for some fluoropolymers (e.g., PVDF, in the appearance of granules) have increased to 300 – 400 % since the beginning of 2020. Therefore, we observe a market-induced rationalization of our fluor-products. Economical and social influences both are already pushing a trend to reduce the use of fluoropolymers to just the applications without any alternatives available. |
| Answer to specific info request 1:  The Annex XV restriction report (Table 9) does not address the variety of uses in the chemical industry. Our products and experiences are heavily connected with this sector, so we focus on contributing to information regarding the chemical industry. Moreover, we share information on the “semiconductor” sector and “fluoropolymer applications” of “petroleum and mining” sector of Annex XV restriction report (Table 9). Because the restriction report is not clear on whether the sectors/derogations apply to the production processes or the products, we strongly emphasize that we concentrate on the equipment used in the production processes of the given sectors and not on the manufactured final products. |
| Answer to specific info request 6:  For detailed information please check the attachment "PFAS Material Options” under section IV and "General Remarks" and "Resistance list 20230424\_PFAS" under section V. Information on socio-economic impacts can be found under section V “CONFIDENTIAL\_20230505\_PFAS consultation\_socio-economic impacts”. The research on alternatives at this point in time is not very dependable. We continue to elaborate solutions for our customers’ applications and plan to add information on alternatives later in the consultation phase. |
| Answer to specific info request 8:  As a supplier for chemically aggressive applications, we keep a list of the resistance of the materials we use against different chemicals. In section V “Resistance List 20230423\_PFAS” there is a compilation of 62 chemicals that, based on internally examined scientifical studies, require the use of fluoropolymers. In our products the given materials are all processed in pure form. Further explanation one can find in the stated document and within our "General Remarks" under section V. We will elaborate socio-economic effects and provide them in a later statement. |

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| 4083 | Date:  2023/05/11 18:27  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Honeywell Advanced Limited  Org. country:  Ireland  Attachment:    Privacy statement:  N/A | General Comments:  Honeywell International Inc. (hereinafter - Honeywell) is a global manufacturer and importer of various fluorinated gases to the European Union (EU), including hydrofluorocarbons (HFC) and hydrofluoroolefins (HFO) refrigerants and their mixtures (blends), primarily used in refrigeration, heating, ventilation and air conditioning (RHVAC), mobile air conditioning (MAC), thermal management systems (TMS) in electric vehicles (EV), propellants in medical dose inhalers (MDI) and insulation foams blowing agent applications, as well as a particular fluoropolymer - polychlorotrifluoroethylene (PCTFE) - used in the primary packaging of medicinal products and medical devices. |
| Answer to specific info request 1:  Honeywell International Inc. (hereinafter - Honeywell) is a global manufacturer and importer of various fluorinated gases to the European Union (EU), including hydrofluorocarbons (HFC) and hydrofluoroolefins (HFO) refrigerants and their mixtures (blends), primarily used in refrigeration, heating, ventilation and air conditioning (RHVAC), mobile air conditioning (MAC), thermal management systems (TMS) in electric vehicles (EV), propellants in medical dose inhalers (MDI) and insulation foams blowing agent applications, as well as a particular fluoropolymer - polychlorotrifluoroethylene (PCTFE) - used in the primary packaging of medicinal products and medical devices. |
| Answer to specific info request 2:  Relevant information will be provided in future submissions. |
| Answer to specific info request 3:  Relevant information will be provided in future submissions. |
| Answer to specific info request 4:  Relevant information will be provided in future submissions. |
| Answer to specific info request 5:  Relevant information will be provided in future submissions. |
| Answer to specific info request 6:  Relevant information will be provided in future submissions. |
| Answer to specific info request 7:  Relevant information will be provided in future submissions. |
| Answer to specific info request 8:  Relevant information will be provided in future submissions. |
| Answer to specific info request 9:  Relevant information will be provided in a stand alone, future submission on this topic. |
| Answer to specific info request 10:  Relevant information will be provided in future submissions |

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| 4084 | Date:  2023/05/12 03:49  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  KITZ Corporation supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV. |

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| 4085 | Date:  2023/05/12 05:12  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  I agree with the comments of the Japan Fluorochemical Products Council (FCJ). I attach my comments in Section IV. |

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| 4086 | Date:  2023/05/12 05:14  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  I agree with the comments of the Japan Fluorochemical Products Council (FCJ). I attach my comments in Section IV. |

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| 4087 | Date:  2023/05/12 07:26  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  VENN co.ltd  Org. country:  Japan  Attachment: | **General Comments:**  - |

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| 4088 | Date:  2023/05/12 07:53  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  FluoroTechnology Co.,Ltd.  Org. country:  Japan  Attachment: | General Comments:  Fluorine compounds having both a hydrofluoroether group and a reactive group have been used extensively as antifouling agents for hard coating agents.  A hard coating agent is a coating agent for the purpose of preventing scratches on various surfaces. After coating, this coating agent is cured by UV irradiation to form a film.  A fluorine compound having both a hydrofluoroether group and a reactive group is used by being added to the hard coating agent.  After coating, the hard coating agent to which this fluorine compound is added exhibits both the function of preventing stains such as fingerprints, water stains and adhesives, and the function of low friction.  Oil repellency and a low coefficient of friction are required to prevent fingerprints and smudges. There is no substitute substance because there is no oil-repellent substance other than fluorine-based compounds in the world. Also, the fluorine compound has an optically low refractive index. Reflected light can be reduced by coating optical parts such as lenses and transparent films with a hard coating agent containing a fluorine-based compound to a thickness of about 0.1 μm. Reducing reflected light results in a 3-5% improvement in transmitted light transmittance. Other various resins have a high refractive index and cannot achieve such a reflected light reduction rate. |
| Answer to specific info request 1:  Additives for imparting fingerprint adhesion for hard coats, Low refractive index additive for hard coat, Anti fouling Additives |
| Answer to specific info request 2:  There are no PFAS emissions during the manufacturing and use stages. 100% emissions at disposal stage. The service life is the same as the equipment used. |
| Answer to specific info request 3:  This product is often used in plastics at the disposal stage. If the target is incinerated, it will be decomposed into HF |
| Answer to specific info request 5:  Since it is an additive, the production volume is estimated to be less than 100 tons per year. |
| Answer to specific info request 9:  There is no information that it changes into a precursor of the substance. |

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| 4089 | Date:  2023/05/12 08:06  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  I agree with the comments of the Japan Fluorochemical Products Council (FCJ). I also attach my comments in Section IV. |

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| 4090 | Date:  2023/05/12 10:17  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  We, TLV CO., LTD, agree with the comments of the Conference of Fluoro-Chemical Product Japan (FCJ) "Comment on Proposed Restriction of PFAS on Apr. 25, 2023" attached in Section IV. |

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| 4091 | Date:  2023/05/12 11:31  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  OKUMURA ENGINEERING supports the statement made by FCJ on the issues of proposed restriction,as per attached in Section IV. |

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| 4092 | Date:  2023/05/12 11:45  Content:  Scope or restriction option analysis  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:  Austria  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Customer information, Information of the complete industrial sector, Secret and strategic company information | General Comments:  General comments: Semiconductor devices (“chips” or “integrated circuits”) are important components of many electronic devices. This “chips” are extremely complex to manufacture whereby up to 2000 process steps, which will require a production time up to 26 weeks. In this semiconductor industry, fluoropolymers are used for transport of ultrapure water and other process media due to the excellent leach out behaviour, cleanliness, resistance against bio-film, high temperature resistance, chemical resistance, excellent mechanical properties and long lifetime performance. PTFE is an inert material, and therefore absolute necessary to transport highest grades of ultrapure water required for the wet chemistry process in semiconductor factories to manufacture node sizes of 14,12,10,8,5, 3 nanometer. Ultrapure water in this industry is one of the most used media required in the wafer production, Ultra pure water is used in many process steps and the quality of water is most important for the chip factory output (yield).  Considering that the Semiconductor industry was estimated having a global sale of 600 Billion$ (in 2022) and a further required growth up to 1 Trillion$ till 2030, because of the increasing demand on high quality chips in many applications (cars, electrified cars, KI, AI, data centers, 5G, etc,…) this industry plays an essential socio-economic role worldwide.  Without Fluoropolymers like PTFE the ability to produce semiconductor will be put at high risk.  Banning them in Europe will put the European Chips Act and the whole European economy at high risk.   Specific product “PTFE Diaphragm”: A PTFE Diaphragm valve is used in ultra-pure-water systems for example in the semiconductor manufacturing process, Photovoltaic Cell manufacturing, green hydrogen electrolysis etc. In order to supply water with the highest level of purity (no metal ions, no contamination of other anorganic and organic material…). In the valve, the diaphragm mainly serves the following functions: (1) besides the main body of the valve (usually made out of PVDF, another fluoropolymer) it should provide a low-friction, low-surface-energy, pure, low-leach-out contact area to the flowing ultra-pure-water, (2) to provide high water throughput with low flow resistance independent of pressure, no dead flow areas where particles can accumulate (open position of valve) and (3) water tight sealing properties in closed position of the valve. In order to fulfill above mentioned technical and functional requirements, the diaphragm material needs to: - Provide lowest leach-out-levels of metallic ions, inorganic and organic material meeting the (current and future) stringent norms and restrictions of e.g. the semiconductor industry - Be formable and processable o To (thermo)form curvatures o to provide fine geometrical details like sealing lines (feature size: radius ~ 0.3 mm) o for incorporating of metallic pins for opening and closing the diaphragm via welding - provide a high level of mechanical flexibility and life-time (“flex-life”) for frequent opening and closing the valve - at the same time o provide enough mechanical strength (tensile, flexural, shore hardness) to savely incorporate the metallic pin (~ 10 kN tensile force) and to withstand the combination of hydrodynamic pressures present during operation (10bar @ 80-90°C) and the forces applied through the metallic pin o provide a low level of “cold flow” (smaller than 10 %) over time when pressed together (otherwise valves tend to leak over time) - have lowest level of coefficient of friction and surface energies when in contact with water - be thermally resistant and form-stable up to process temperatures of 80-90°C - be cost effective and easy to process  To the best of our knowledge, PTFE (and especially modified PTFE) is the only material to date which fulfills beforementioned requirements. PTFE diaphragms make up only a minor fraction of material and cost in ultra-pure-water systems. However, the added value for the applications and industries (EU chips act, EU green deal, hydrogen economy…) PTFE diaphragms are utilized clearly highlight the importance and benefits of this technical product. Furthermore, we are convinced that PTFE diaphragms can be safely manufactured, packed, applied and treated after end of life with no significant emissions of PFAS into the environment.  We therefore request full exemption of fluoropolymers like PTFE from the restriction proposal. |
| Answer to specific info request 1:  Fluoropolymers are included in the use category “semiconductor manufacturing equipment & infrastructure” as described in Annex A, table 9 of the proposed restriction, and identified RO2 with a 12 years derogation. However, the Annex XV restriction report does not cover all relevant and essential uses of fluoropolymers in the critical sector “semiconductor manufacturing”: PTFE Diaphragms in Ultra-Pure-Water Systems, which is necessary for the supply of ultra-pure water is not listed in Annex A, table 9 and therefore need to be added to Annex XV. |
| Answer to specific info request 2:  Confidential attachement |
| Answer to specific info request 7:  a) The industry especially semiconductor industry has a growing demand on PVDF piping systems and therefore also PTFE diaphragm valves, because of the technical benefits Fluoropolymers offer for this high-grade production processes. Specially for this application our company is producing Diaphragms valves. Further details see confidential attachement. b) In the valve, the diaphragm mainly serves the following functions: (1) besides the main body of the valve (usually made out of PVDF, another fluoropolymer) it should provide a low-friction, low-surface-energy, pure, low-leach-out contact area to the flowing ultra-pure-water, (2) to provide high water throughput with low flow resistance independent of pressure, no dead flow areas where particles can accumulate (open position of valve) and (3) water tight sealing properties in closed position of the valve. In order to fulfill above mentioned technical and functional requirements, the diaphragm material needs to: - Provide lowest leach-out-levels of metallic ions, inorganic and organic material meeting the (current and future) stringent norms and restrictions of e.g. the semiconductor industry - Be formable and processable o To (thermo)form curvatures o to provide fine geometrical details like sealing lines (feature size: radius ~ 0.3 mm) o for incorporating of metallic pins for opening and closing the diaphragm via welding - provide a high level of mechanical flexibility and life-time (“flex-life”) for frequent opening and closing the valve - at the same time o provide enough mechanical strength (tensile, flexural, shore hardness) to savely incorporate the metallic pin (~ 10 kN tensile force) and to withstand the combination of hydrodynamic pressures present during operation (10bar @ 80-90°C) and the forces applied through the metallic pin o provide a low level of “cold flow” (<10 %) over time when pressed together (otherwise valves tend to leak over time) - have lowest level of coefficient of friction and surface energies when in contact with water - be thermally resistant and form-stable up to process temperatures of 80-90°C - be cost effective and easy to process - No biofouling - Low particle accumulation - Good compromise between flexibility, tensile strength and flexural strength - Low permeation - Very low particle shedding - Low moisture absorption - Physiologically non toxic - Very good thermal stability and electrical properties - Excellent long term performance To the best of our knowledge, PTFE (and especially modified PTFE) is the only material to date which fulfills beforementioned requirements. c) Every state of the art semiconductor fab worldwide uses PVDF piping systems where PTFE diaphragm valves are used to transport ultra pure water for cleaning of microchips. Further details see confidential attachement. d) There are several possible materials to consider when manufacturing a diaphragm for fluid control : 1. Rubber diaphragms: Rubber diaphragms are compression molded of synthetic rubber with a nylon fabric mesh positioned within the rubber to improve the diaphragm’s flexing characteristics. The following are the rubber diaphragm materials available: o Neoprene is an exceptional general-purpose, low-cost diaphragm. Designed for non-aggressive chemical applications such as water-based slurries, well water or seawater, it provides good flex life and abrasion resistance. o Buna-N is used in applications involving petroleum/oil-based fluids such as leaded gasoline, fuel oils, kerosene, turpentine and motor oils. In wide use throughout the fuel processing industry, Buna-N is also referred to as nitrile and provides moderate flex life and moderate abrasion resistance. For food and beverage applications, versions are available that comply with FDA 21 CFR 177 standards. o EPDM is suited to extremely cold temperatures and is an economical alternative when pumping dilute acids or caustics. EPDM diaphragms are in use in the manufacturing, food, pharmaceutical and paint/ coating industries. The material exhibits good flex life and moderate abrasion resistance, and it is available in versions that comply with FDA 21 CFR 177 standards. EPDM is also a good choice where statically dissipative materials are required. o Viton is excellent for extremely hot temperatures and provides exceptional performance with aggressive fluids such as aromatic/chlorinated hydrocarbons and strong, aggressive acids. Viton is often the only diaphragm material suitable for applications where harsh chemicals are used because of its high temperature limit and chemical resiliency. It provides moderate flex life and moderate abrasion resistance. However, Viton is made out of FKM which is another Fluoropolymer. What Rubber does not provide for the specific use case: - Excellent leach out behaviour / cleanliness - Excellent cold-flow behaviour - Excellent flex-life - Low surface energy - No biofouling - Low particle accumulation - Low flow resistance, lowest surface roughness values - Good compromise between flexibility, tensile strength and flexural strength - Good weldability - Low permeation - Very low particle shedding - Excellent temperature / mechanical properties - Low moisture absorption - Very good thermal stability and electrical properties 2. Thermoplastic elastomer (TPE) diaphragms: TPE diaphragms are manufactured by injection molding. As a result of their dimensional stability and tensile strength, TPE diaphragms do not need fabric reinforcement. Following are the available types of TPE diaphragms: o Polyurethane is a general-purpose diaphragm for nonaggressive chemical applications such as water, wastewater and seawater. It provides excellent flex life, abrasion resistance and durability at an economical price. o Wil-Flex provides a low-cost alternative to PTFE with a cost comparable to neoprene. Made of Santoprene, Wil-Flex is used with acidic and caustic fluids such as sodium hydroxide, sulfuric or hydrochloric acids. Exhibiting flex life, abrasion resistance, temperature range and durability, it is widely used in the chemical process, food, pharmaceutical and wastewater industries. Versions of Wil-Flex are available that comply with FDA 21 CFR 177 standards for food and beverage applications. o Saniflex is suitable for food processing applications. Made of Hytrel, it exhibits good flex life and excellent abrasion resistance. Hytrel also offers superior sealing or seal energizing due to its low compression set characteristics. Saniflex versions are available that comply with FDA 21 CFR 177 standards. o Geolast exhibits enhanced oil-resistance and low oil swell making it ideal for petroleum industry applications. Equivalent to nitrile (Buna-N), Geolast provides moderate flex life and good abrasion resistance over a wide temperature range at a lower cost than fabric-reinforced Buna-N. What thermoplastic do not provide for the specific use case: - Excellent leach out behaviour / cleanliness - Excellent flex-life - Low surface energy - No biofouling - Low particle accumulation - Low flow resistance, lowest surface roughness values - Good compromise between flexibility, tensile strength and flexural strength - Very low particle shedding - Excellent temperature / mechanical properties - Low moisture absorption - Very good thermal stability and electrical properties - Excellent long term performance Besides PTFE, PFA (another Fluoropolymer) might be suitable as a diaphragm material. However, as compared to PTFE, PFA comes short in flex-life, tensile strength and cost. Diaphragms are also manufactured out of metals like nickel, silicon and bimorph materials , however they also come short in most of the functionalities (like flexibility, leach-out, smoothness…) when it comes to the current and future requirements of the semiconductor industry. In our opinion there is no technically and commercially feasible alternative to PTFE diaphragm. e), f) In our opinion there is no technically and commercially feasible alternative to PTFE diaphragm. g) See confidential attachement The effect of banning Fluoropolymers like PTFE could have a substantial impact on the whole strategic social, environmental and economic plans of the EU, and for sure the European value chain. Impact on EU Strategies: - Green House Gas emission target - Green deal - REPowerEU - Digitalization Strategies - European Chips Act - … |

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| 4093 | Date:  2023/05/12 12:21  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Austria  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Secrete company and customer information | General Comments:  ECTFE fluoropolymers used for chlorination systems Why Fluoropolymers in the Chemical Industry for chlorine?  Chlorination is the process of adding the chemical element chlorine to water/sea water/sewage water. The main reason for chlorination is disinfection of drinking, service and waste water (waste water treatment facilities, desalination, cooling water, …) as well as water treatment in public, thermal baths or for bleaching. There are three main methods of adding chlorine:   Chlorine (Cl2 in gaseous form)  Hypochlorites such as sodium, calcium and potassium hypochlorite (NaOCl, Ca(OCl)2, KOCl)  Chlorine dioxide (ClO2) When dissolved in water, chlorine converts to an equilibrium mixture of chlorine, hypochlorous acid (HOCl) and hydrochloric acid (HCl). In acidic solution, the main chemical elements are Cl2 and HOCl, whereas in alkaline solution, effectively only ClO− (hypochlorite ion) is present. Very small concentrations of ClO2−, ClO3−, ClO4− (chlorites, chlorates, perchlorates) are also developed in these chemical reactions. All these developed chemicals need to be handled by a suitable material during production, storage, handling, transport and usage (e.g. chlorination lines made from pipes, fittings and valves, storage tanks made corrosion resistant material, …).  Depending on the application, chlorine is added to the existing medium (water, waste/process water,..) in a certain concentration, in some cases the concentration is low (for drinking water in Europe the permissible concentrations are smaller 3 mg/l, in the United States smaller than 4,3 mg/l ), for industrial applications the concentration goes up to 15% or even to chlorine in technically pure form. In order to supply chlorine with higher concentrations than 4,3 mg/l to the dosing stations or to transport chlorine in concentrations biger than 4.3 mg/l safely, piping systems and tanks made of fluoropolymers (ECTFE, at pH values smaller12 also in PVDF) are essential.  On the one hand chlorination is a method of water purification to make it suitable for human consumption as drinking water. In many parts of the world drinking water chlorination is essential and saving lives. Adding chlorine is the most common type of drinking water disinfection and it is absolutely necessary (more than 1 billion people in the world do not have access to clean drinking water). Disinfection kills bacteria, viruses, and other microorganisms that cause disease and immediate illness. On the other hand chlorination is absolutely necessary to ensure the suitability and quality of water for different industrial applications. A seawater intake system has to be designed and constructed to ensure a sufficient seawater supply regarding the quantity and quality for the end user (e.g. power stations, desalination plants, mines). Such seawater intake systems are a fundamental part for end users and they have to be designed with great care. The design has to guarantee the requirements of the end users, protect the whole equipment, the intake system itself and has to minimize any risk for the environment (marine life). To ensure the quality of the seawater chlorination with is necessary. Chlorination is done using pipes with diameters mainly in the range from OD20 mm up to OD110 mm, which are installed and fixed at the inside or at the outside of the seawater intake pipes. Thermal power plants have very large requirements of raw water which is mainly used for condenser cooling and to a smaller extent for the production of demineralized water (DM water) which is used as boiler feed water to produce steam. Sea water, water from lakes and rivers is very often the source of raw water for power plants. Chlorination/disinfection with concentrations bigger than 4.3 mg/l is also indispensable in the process industry (semi-conductor industry, pharmaceutical industry-please see “ANNEX 4: Reference ECTFE\_transport of sodium hypochorite\_Vaccine production” attached). Production, storage, transport and use of chemicals and other hazardous materials can inevitably carry potential risks. Moreover, history has shown that accidents can not only have economic impacts, but also irreparable consequences on human lives and the environment. Mitigating such risks through rigorous safety management whilst simultaneously ensuring efficiency and availability is a major challenge for today’s worldwide chemical industry.  In our view, the Annex XV restriction report does not cover relevant and essential uses of fluoropolymers in the critical sector “chemical industry”: Pipelines, storage tanks and transportation containers for the handling of chemicals. Fluoropolymers are mechanically solid, chemically resistant and stable even in harsh and corrosive environments.  We request full exemption of fluoropolymers used in industrial applications from the restriction proposal. |
| Answer to specific info request 1:  The specific Sector “ECTFE fluoropolymers used for chlorination systems” is not listed in Annex XV. |
| Answer to specific info request 2:  For this specific application extruded ECTFE pipes, injection moulded ECTFE fittings and valves are used. Furthermore semi-finished products in ECTFE in form of extruded round bars (up to OD = 120 mm) are needed to make machined fittings, welding rods (circular profile: 3 and 4 mm) are needed as accessories. Sheets are used for construction and inside lining of storage tanks and transportation containers. According to our supplier Solvay, ECTFE is already produced without the use of fluorinated polymerization aids, thus ECTFE has a very low potential for leaching of small molecular PFAS. During manufacturing: There is a certain amount of emissions when fluoropolymers are processes at elevated temperature in the thermoplastic state. While the majority of the emissions is HCl and HF, there is no detailed information available if the emissions contain small molecular PFAS. In our facility, the main parts of the extrusion line with the highest temperatures (thus the areas where emissions are most likely to occur) are covered with a ventilation hood to suck of fumes/emissions above the extrusion line. The off gases are then cleaned in gas scrubber, before released into the environment. Measurement have shown that some small molecular PFAS accumulate in the water of the gas scrubber, thus cleaning the off-gasses is a proven way to reduce emissions. Precise work and proper work instructions avoid loss of fluoropolymers during the production in our facilities. Material from the starting process as well as chips from cutting are collected and added again to the extrusion process (internal recycling). Material which cannot be processed again is stored in containers and sent for incineration following Austrian laws for handling waste (>850 °C effectively destroys PFAS during incineration). Storage and handling Proper Packaging avoids PFAS loss during the transportation and storage. After production, products are packed sold in sales units like: • Pipes: OD 20 – 160 mm diameter; Length = 5 m; packed in plastic foil • Fittings and valves: OD 20 – 110 mm diameter; packed in plastic foil and proper cardboard • Round bars: OD 20 – 110 mm diameter; Length = 1 m; packed in plastic foil • Welding Rod 3 -4 mm diameter (2 kg Spool); packed in plastic foil and proper cardboard • Sheets from 2 mm up to 50 mm thickness, wrapped in plastic foil, packed in cardboard boxes. During the production, storage and handling of ECTFE pipes, fittings, valves, semi-finished products no environmental pollution is expected. The material is inert and very stable, especially at ambient temperature. The use-phase: Products are used in the following specific sub-uses: • ECTFE piping systems are used for the transport of chlorine in its different forms. Components made of ECTFE ensure the safe transport of most critical media for human beings and environment. Chlorine in its different forms does not leach out any elements, which belong to the group of PFAS. During the use in the temperature range from 20-120°C emissions from ECTFE do not occur (below detection limit), because the material is extremely stable, inert and does not degrade into small molecular substances over the whole lifetime. End-of-life: Equipment which is decommissioned after service life (~25 years depending on the application) could be collected and deposited or incinerated according to the state of the art and according to laws in place for handling waste. Incineration destroys PFAS substances. See link: https://www.sciencedirect.com/science/article/pii/S0045653519306435?via%3Dihub%E2%80%A8 |
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ECTFE is an essential material for handling chlorine chemicals used for water disinfection. a) see confidential document attached b) Various, reliable, internationally accepted chemical resistance lists/tables (e.g. DVS Codes 2205-1, ISO TR10358) , information supplied by the raw material supplier (company: Solvay) confirm that ECTFE is the only safe and long term solution for the transport of chlorine in its different forms for concentrations bigger 4,3 mg/l, it is chemical resistant no matter how the temperature (up to 120°C) and pH value are, while other materials (e.g. PE, PP, PVC, PVDF, ABS, PA, …) can only handle low concentrations (smaller than 4,3 mg/l) or higher concentrations for a very limited lifetime (maximum 2-10 years) including the risk of unexpected immediate failures-please see “ANNEX 3: ISO\_PRF\_TR\_10358” attached). Also metals (steel, copper) do not enable such a universal chemical resistance, at least not in a cost effective way. In addition to the outstanding chemical resistance ECTFE piping systems meet all further requirements for such applications: • Internal pressure resistance of pipes and fittings • Temperature resistance • UV resistance • Flexibility • Weldability • Suitability for below ground applications (also underwater application) • Availability of pipes, fittings, valves and special parts (complete supply range) c) Apart from our suppliers for ECTFE (Solvay) and the companies producing the ECTFE piping systems for chlorination water treatment system, the largest impact is expected for the shipping industry and the companies in the need of water/sea water/process water. Affected industrial applications in general: Whole chemical industry, steel industry, refinery and petrochemical industry, metallurgy industry, mining industry, pharmaceutical industry, power industry, viscose industry, semiconductor industry and all users of critical chemicals. d) Only high grade piping systems made of high grade thermoplastics, such as ECTFE, offer safety, reliability and significant improvements in performance, installation and safety during operation. Alternatives like PE, PP, PVC, ABS, PVDF, PA and metal pipes can only handle low concentrations or higher concentrations for a very limited lifetime including the risk of unexpected failures, which would have dramatic influence on the environment (death of all marine life,...). Please see ANNEX e) ECTFE has become established over the last decades and represents the current state of the art, as the old systems has been replaced due to the large number of problems. Currently for this application no other solution based on polymeric products seams feasible due to the extreme operating conditions, that require a special combination of temperature and chemical resistance (in special the difficult behavior of chlorine in watery solutions with developing further elements, varying pH value). Please see ANNEX f) Alternative piping systems do not offer a sufficient resistance, especially if the chlorination process and its special chemical behavior in watery solutions are considered (changing pH value, development of other chlorine compounds). Other piping systems than the ones made of ECTFE are not resistant in the same way and would corrode and leak. Alternatives would be available but are impacted by the PFAS restriction proposal as well. It would be possible to use PVDF (for chlorination lines with a pH value smaller 12), FEP or also PFA. Using PE, PP, PVC, ABS, PVDF, PA, steel, copper would not allow to use chlorine in its different forms with such a high efficiency. We are in permanent contact with raw material suppliers, and we are always considering to include products made of new developments (regarding the raw materials) in the product range. Concerning raw materials with improved resistance to chlorine the raw material supplier for HDPE are promoting special grades with a resistance to 4,3 mg/l (4,3 ppm) chlorine, whilst for the chlorination process a resistance to concentrations up to 15 000 mg/l (15 000 ppm) and much higher is required. Based on this fact/example a material, that withstand such high concentrations, will not be available within the next 10-15 years. Please see: ANNEX 5: Plastic Europe technical paper PE chlorine Mar 2007” g) At first glance the impact for our company, the competitors, the customers and the suppliers seems to be not drastically, banning ECTFE and other fluoropolymers would increase the cost of water treatment/disinfection. The biggest impact is expected for making water suitable for human consumption as well as enabling the use of seawater as well as water from lakes and rivers for power station. The demand on water for human beings, water for agricultural use, water for power station will increase in the future in a significant way. Human-caused global warming is having a dramatic impact on people, biodiversity and water. Warmer temperatures, increased evaporation and a changed precipitation regime have a direct impact on the water balance. For industries dependent on disinfecting water, the economic impact is difficult to quantify, but please see below three main effects: Shortage of water (drinking water, water for agriculture, process water) causes sicknesses. Polluted water and lack of sanitation cause and spread diseases and pose extremely high health risks. Millions of people die each year from preventable waterborne diseases, including five million children. According to the World Health Organization (WHO), 88% of all diseases can be traced back to polluted water. Shortage of water (drinking water, water for agriculture, process water) causes hunger A water disaster quickly turns into a famine. Because agriculture and animal husbandry are directly depending on water. Shortage of water (drinking water, water for agriculture, process water) creates conflicts The "struggle" for water leads to political disputes and conflicts within and between states. 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| 4095 | Date:  2023/05/12 12:45  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:  <redacted>  Org. country:  Austria  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Secret company and customer information | General Comments:  Specific Use case: Sealings/gaskets and O-rings made of fluoropolymers  Why Fluoropolymer sealings/gaskets/ in the Chemical Industry?  Detachable connections in piping systems are essential for e.g., easy replacing valves and devices in pipeline assembly. Sealings are also an indispensable functional part in valves used for chemical applications. The most used detachable connections in chemical installations are the screw connection (union) and in the case of larger pipe diameters, the pipes are detachably connected using flange connections (consisting of stub flange, backing ring and sealing/gasket). Flange connections are also needed in case of connecting systems made out of different materials (e.g., connecting piping systems made of thermoplastic materials to steel). There are numerous applications where the use of traditional elastomers is ruled out (such as EPDM, NBR). Aggressive chemicals or extreme temperatures can destroy conventional O-rings. This ultimately leads to leakage and may lead to environmental and worker safety issues. Proper O-rings (standardized parts in correlation with DIN ISO 3601) and flange gaskets ensure the tightness of such systems. They create a seal through the deformation of the cross-section and the rebound elasticity of the elastomer in the clearance space. They are installed axially and radially and can be used in static and dynamic applications in their respective areas of application. FPM is a copolymer made of highly fluorinated hydrocarbons and developed during the 1950. FPM is compatible with hydrocarbons, lubricating and fuel oil, hydraulic oil, gasoline, kerosene, vegetable oils, alcohol and acids up to technically pure concentrations. Most important is that FPM performs well in harsh environments, in temperature extremes and with critical chemicals. The rubber is ideal for operating in hot and corrosive environments in temperatures up to 200 °C. Its highly elastomeric properties guarantee an even pre-tensioning at the sealing point and ensure reliable sealing and high resistance to aggressive media. For even more demanding applications involving most aggressive media O-rings made of FFKM (perfluoro rubber) offers outstanding and nearly universal resistance to chemical influences. FFKM sealings can be used in a wide temperature range from -30°C up to +334°C. FFKM combines the elastic properties of perfluoro rubber with the chemical resistance of a PTFE material. FFKM O-rings can be used wherever an elastomer’s chemical resistance (even the one of partly fluorinated elastomers) is insufficient. Gaskets made of expanded PTFE (ePTFE) have been developed for the application with most aggressive chemicals and also for the use in high purity piping systems to provide a leak-free seal and laminar flow in joining area, as well as highest purity. They are an essential part of high purity piping system and enable the water purity needed for modern computer chip production,  Fluorinated elastomers in general cover most critical chemicals-please see below some examples:  Sulfuric acid with a concentration of 98% Oleum Nitric acid with a concentration of 98% Hydrochloric acid up to 37,5% and also in gaseous form Hydrofluoric acid up to 90 % and also in gaseous form Chromic acid, technical grade Sodium hydroxide and potassium hydroxide with a concentration of 50% Organic and inorganic chlorine compounds, technical grade  Looking at ISO TR 10358 it becomes evident that PTFE has an almost universal chemical resistance, whereas other polymers have limitations in terms of temperature and chemicals. The same is true for ISO TR 7620, that provides information about the chemical resistance of fluorinated elastomers. Please see confidential attachement: ANNEX 6: ISO\_PRF\_TR\_10358 ANNEX 7: ISO\_TR 7620\_Rubber materials-Chemical resistance  In the semiconductor industry, mainly fluoropolymers are used for the transport of ultrapure water and also for other process media. The reasons for the use are the outstanding properties like excellent leaching behavior, purity, resistance to biofilm, high chemical and temperature resistance. Fluoropolymers for the piping systems like PVDF are inert from the chemical point of view (due to the fluorine in the molecular chain). Inertness of a material is a requirement of highest priority for the transport of ultrapure water. Furthermore the use of fluoropolymers like PVDF guarantee a long service life. For such piping systems detachable connections are essential (they are of highest importance), again only sealings made of fluorinated elastomers meet the requirements on purity, inertness, and chemical resistance. In our view, the Annex XV, Table 8 restriction report does not cover relevant and essential uses of fluoropolymers and fluoroelastomers in the critical sector “chemical industry”: Pipelines, storage tanks and transportation containers for the handling of chemicals are frequently used because they are mechanically solid, chemically resistant and stable even in harsh and corrosive environments.  We request full exemption of all fluoropolymers such as PVDF; ECTFE, FEP, PFA and PTFE as well as all fluoroeleastomers such as FPM and FFKM fro the restriction proposal. |
| Answer to specific info request 1:  The specific sector “Sealings/gaskets made of fluoropolymers used for dangerous/most aggressive chemicals” process is not listed in Annex XV, Table 8. |
| Answer to specific info request 2:  FPM/FFKM O-rings for these specific applications typically have a thickness of 3,53 mm (for parts OD20-OD32 mm) and a thickness of 5,33 mm (for parts OD40-OD90mm) SealClean gaskets made of ePTFE for flange connections have thickness of 3,0 mm (diameters are in the range from 15,3 mm to 281 mm, covering pipe outside diameters from 20 mm to 315 mm). Today most fluorinated elastomers are produced using fluorinated polymerization aids that may remain in extremely small amounts (ppm) within the fluorinated elastomers and have the potential to leach-out during the use phase. To reduce the risk of small molecular PFAS to be emitted from fluoropolymers, it is desirable to produce them without fluorinated polymerization aids. Our company will change to fluoropolymers manufacted without fluorinated polymerization aids when available. During manufacturing: There is a certain amount of emissions, when fluoropolymers are processed at elevated temperature in the thermoplastic phase. While the majority of the emissions is HCl and HF, there is no detailed information available if the emissions contain small molecular PFAS (this information is based on statements of the suppliers, who are making the manufacturing of the sealings/gaskets). In this case sealings/gaskets are not produced in the facilities, they are bought from highest-quality suppliers. In our facilities unions and valves are assembled, and fluorinated seals are installed accordingly. During the production/assembling at ambient temperature, we do not expect any environmental pollution by the mentioned fluoropolymers. The suppliers of the fluorinated elastomers are aware of all these facts but continue to emphasize, that there must be differentiated in a very detailed way between the term “PFAS”. Please see below a statement published by the company "Confidential" (summary done by us without any substantive changes in content): There are significant distinctions between the chemical and physical properties of fluoropolymers like PTFE and other materials most often associated with the term PFAS. PTFE does meet the very broad definition of the term despite the important distinctions. Often, agencies, regulators, scientists or media may use the acronym PFAS when the specific point being made is only accurate for certain PFAS, for example non-polymers such as PFOA. "PFAS" are, for example, described as mobile in the environment. PTFE/FFKM/FPM, as fluorinated elastomers, are not mobile in the environment. Please see confidential attachement Storage and handling All components are specially packed to ensure no contamination is taking place in the supply chain till the products are installed (e.g., chemical plants, semiconductor fab). During the production/assembling of valves, unions with fluorinated elastomer gaskets, no environmental pollution is expected. Proper packaging avoids PFAS loss during the transportation and storage. After production, products are packed like described below: • Fittings (unions in special), valves with fluorinated sealings, ePTFE gaskets: packed in plastic foil and proper cardboard The use-phase: Products are used in the following specific sub-uses: • Products (unions, flanges, valves with fluor seals etc.) are used as most important parts in piping systems for the transport of critical/dangerous chemicals or high-purity water under controlled conditions. It is ensured that no fluorinated elastomers are released into the environment. It must be further considered that the elastomers are inserted in bodies of thermoplastic polymers (PVDF, ECTFE). The sealing materials are inert and do not degrade into small molecular substances over the whole lifetime. End-of-life: Equipment which is decommissioned after service life (~ 10-15 years depending on the application) will be deposited under strict governmental rules (hazardous waste) in dedicated landfills or will be incinerated. The products are stable and will not degrade into low molecular PFAS. Please see ANNEX 1 in the confidential attachement for further information about the incineration of PTFE. Studies found that at typical incineration temperatures no PFAS of environmental or toxicological concern are generated. |
| Answer to specific info request 6:  The processes, for which sealings/gaskets and O-rings made of fluorinated elastomers are used, include all applications for dangerous/most aggressive chemical, where in case of leakages great harm is caused to the environment and mankind (e.g. media dangerous to water). a) details on the annual tonnage see confidential attachement b) Various, reliable, internationally accepted chemical resistance lists/tables (e.g., ISO TR 7620, ISO TR 10358) and information provided by the manufacturers of FPM, FFKM and ePTFE confirm that only fluorinated elastomers are chemically resistant to most critical, high concentrated chemicals at ambient temperatures, as well as at high temperatures (up to 260°C). See confidential attachement c) Apart from us and our competitors and suppliers for FKM/FPM/ePTFE/PTFE coated gaskets/sealings, the largest impact is expected for all companies producing and using/ chemicals. Also the semiconduction industry and other sectors needing ultra-pure water will not be able to maintain the water quality without FPM, FFKM and ePTFE/PTFE products. Affected industrial applications in general: e.g., whole chemical industry, steel industry, refinery and petrochemical industry, metallurgy industry, mining industry, pharmaceutical industry, power industry, viscose industry, semiconductor industry and all users of critical chemicals. d) Aggressive chemicals or extreme temperatures can destroy conventional O-rings, sealings, gaskets. This ultimately leads to leakage. Beside repetitive shut-downs due to replacements of not proper sealings for long term application, there remains also big risk for the environment (pollution) and human beings. See confidential attachement e) Sealings/gaskets made of fluoropolymers have been established since many decades for applications with most aggressive chemicals and high-purity applications, where other systems fail immediately or do not show the same excellent performance. For these applications no other solution based on polymeric products seems feasible due to the extreme operating conditions, that require a special combination of temperature, mechanical properties and chemical resistance. The time expected to be required for substitution cannot be estimated, but at the moment there are no alternatives available with the same performance. There is a clear reason why fluoropolymers and -elastomers are used in these most critical applications. Fluoropolymers have an extremely high price and are only used where no other solutions are available. See confidential attachement f) Only high grade piping systems made of high grade thermoplastics, such as PVDF, ECTFE, FEP, PFA offer a guarantee for safe transport of chemicals. Such piping systems need detachable connections in piping systems and valves made of the same high performance materials. Detachable connections and valves need sealings/gaskets, which offer the same safety and reliability, again only fluorinated sealings are offering these properties. Alternatives like EPDM, NBR, PA, PU, ACM polyacrylate, can only handle low concentrations or higher concentrations for a very limited lifetime. As a result the risk of unexpected failures, which would have dramatic influence on the environment and human beings working in the chemical industry. We are in permanent contact with raw material suppliers, and are always considering to include products made of new developments (regarding the raw materials) in the product range. Based on this permanent and ongoing technical exchange, which also affects new developments, it cannot be assumed that there will be seals on the market in the next decade that will meet the requirements for chemical resistance. See confidential attachement g) At first glance the impact our company, the competitors, the customers and the suppliers seems to be not drastically, if just the figures/numbers are considered, but banning fluorinated elastomers (used for sealings/gaskets) and other fluoropolymers would increase the costs significant for the whole chemical industry and all industries using those chemicals. Detailed information on the socio-econmoic impacts are shwon in the confidential attachement. For industries dependent on seals, the economic impact is difficult to quantify, but it must be aware (beside of numbers), that banning seals made of fluorinated elastomers would decrease safety for people and the environment throughout the chemical industry. What can happen in chemical plants due to malfunctions / failures/not proper materials in the chemical industry should never be forgotten in Europe due to accidents like the Seveso disaster in Italy (north of Milano, 10th of July, 1976). It would be impossible for the semiconductor industry to continue producing high quality products (chips), as only fluorinated seals ensure high quality due to purity, chemical resistance and inertness. A ban would contradict the European Chips Act, that desperately tries to attract chip manufactures to build fabs in Europe. Last but not least it needs to be mentioned, that fluorinated elastomers are indispensable components in the following industrial sectors • Aircraft sealing and surface protection • Automotive industry • Gaskets for industrial applications • Packing for industrial applications Banning sealings/gaskets made of fluorinated elastomers would not only cause harm our business and the business of suppliers/competitors, but to all companies and end users in the chemical industry, semi-conductor industry, agricultural industry, infrastructure, power industry, automotive and aircraft industry. Further information see, confidential attachement. |

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| 4096 | Date:  2023/05/12 13:04  Content:  Hazard or exposure  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:  Austria  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Secret company information. | General Comments:  In our view, the Annex XV, Table 8 restriction report does not cover relevant and essential uses of fluoropolymers in the critical sectors: Chemistry, Semiconductor, Energy...  As shown in the confidential document attached, we already submittet 10 specific case studies. 14 case studies will follow in the next two month. Details on the planned caste studies are given in the confidential attachement. Depending on the completness of submissions from other companies, we plan to submit even more essential use cases if needed.  We request full exemption of Fluoropolymers (PTFE, FKM, FEP, PFA, PVDF, ECTFE...) from the ECHA REACH restriction process.  We want to ensure safe handling of Fluoropolymers along the vlaue chain and would be happy to have a detailed discussion with ECHA on this topic. |

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| 4097 | Date:  2023/05/12 13:11  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes | Answer to specific info request 8:  The alternative in coating are high molecular weight polyesters, however their potential life is lower than PFAS based coatings. |

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| 4098 | Date:  2023/05/12 18:23  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:  Bentley InnoMed GmbH  Org. country:  Germany  Attachment: | General Comments:  Bentley InnoMed GmbH - as a producer of class III and IIb life-saving products - requests an exemption of the regulation of PTFE in general. In the attachment, you find information concerning the content marked above. |
| Answer to specific info request 1:  Implantable medical devices Tubes and catheters Packaging of medical devices |
| Answer to specific info request 2:  a./b. Implantable medical devices: Manufacture phase emission = no emission (we use semi-finished PTFE parts), Use phase emission = no emission (since the PTFE covered stent (implant) does not emit into the environment); end-of-life phase = no emission (It either gets cremated with the patient or buried, depending on the type of funeral. As funerals have very high criteria regarding emission into groundwater, it is impossible that ePTFE, which is not soluble in water, emits into the environment. Crematoria are highly regulated and fulfill respective requirements regarding filtration of flue gas. Packaging, Tubes and catheters are single-use-devices and are biohazard waste after being used for implanting the stent. They are being burned after usage in waste incineration plants, where PTFE is essentially converted to carbon dioxide and hydrogen fluoride, which is converted to non-toxic fluorspar in the filter systems. Therefore: Manufacture phase emission = no emission (we use semi finished PTFE parts), Use phase emission = no emission and end-of-life phase = no emission. |
| Answer to specific info request 3:  PTFE is burned after usage in waste incineration plants, where PTFE is essentially converted to carbon dioxide and hydrogen fluoride, which is converted to non-toxic fluorspar in the filter systems. |
| Answer to specific info request 5:  Since the stent cover (ePTFE) is of very low density, only about 6.6 kg of ePTFE cover material are used to produce more than 100.000 stents. Each stent cures a suffering and helps saving a life. Additional information is provided in the attached document. |
| Answer to specific info request 6:  a. For all sectors (with sub-uses) Bentley InnoMed uses only PTFE while being affected by the sectors mentioned in question 1. The annual used amount of PTFE is given in the following: - ePTFE cover for Stents: ~ 6.6 kg - Tubes and catheters: N/A (amount smaller than medical packaging). - Medical packaging: ~ 40 kg b. The key function of PTFE being used within Bentleys products are as follows: • proven biocompatibility of PTFE and ePTFE graft material with long-term use in vascular implants • long-term evidence for safe clinical use in implant applications • low stiffness of the polymer with very high plastic strain at low stress values • durability and chemical stability in challenging environments • low coefficient of friction • ability to expand the material (allows manufacturing of ePTFE with fibrillary structure) To continue the list, special properties of ePTFE are listed: • non-textile porosity • semi-permeability while maintaining fluid/blood tightness (even expanded) c. Many medical devices require ePTFE or PTFE. Therefore, a large number of medical companies, its suppliers as well as customers (mainly hospitals) are concerned of the PFAS restriction. d. See attached document. e. According to suppliers of PTFE and ePTFE and research organizations, alternatives are not estimated to be available in the near future. It is unclear, whether there will be found any alternatives in general. f. Not applicable. g. As alternatives are not available yet, there will be time-consuming research for ground breaking new materials. Approval of those materials and subsequent product development (including clinical studies) will take more than 13.5 years. For comparison: Development with already known materials are currently taking up more than 7 years. As all approved products contain an ePTFE cover, no alternative will be available after a full ban with a derogation of 12 years. Thus, quality of medical treatment deteriorates. Medical companies, its suppliers as well as customers (mainly hospitals) are concerned of the PFAS restriction and the employment number can not be estimated. |
| Answer to specific info request 8:  Detailed information on alternatives is discussed in the attachment. |

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| 4099 | Date:  2023/05/12 22:42  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  The Rubber Group  Org. country:  United States of America | General Comments:  We believe that there should be an exemption to this restriction for fluoropolymers. Specifically: fluorocarbon, fluorosilicone, TFE/P (Aflas) and FFKM. These polymers are not mobile, are not bio-available, are not soluble in water and do not break down into other PFAS categorized substances. They do not fit the toxicology and environmental components associated with other PFAS categorized materials that do not meet the criteria above. While these polymers are persistent, they fill a unique role in just about every industry that is not achievable through other materials, chemicals or compounds. Their persistent nature is what allows them to fill these gaps in product applications where no other material can. There is no current replacement for these materials. Decisions to list these polymers should be science based and not based on a generalization of the chemical makeup of the compounds. |

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| 4100 | Date:  2023/05/15 02:28  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  We agree with the comments of the conference of Fluoro-Chemical Product Japan(FCJ). Attachthat comment to section Ⅳ. |

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| 4101 | Date:  2023/05/15 02:50  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  フシマン株式会社  Org. country:  Japan  Attachment: | General Comments:  We endorse the comments of the Japan Fluorochemical Products Association (FCJ) and attach their comments in Section IV. |

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| 4102 | Date:  2023/05/15 05:27  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Fujikin Incorporated  Org. country:  Japan  Attachment: | General Comments:  Fujikin supports the statement made by FCJ on the issues of proposed restriction,as per attached in Section IV. |

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| 4103 | Date:  2023/05/15 07:07  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Description of analytical methods  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  We agree with the comments of the Japan Fluorochemical Products Council (FCJ), so we attach the comments in Section IV. |

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| 4104 | Date:  2023/05/15 08:40  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  We reject this undifferentiated approach of group regulations and request that fluoropolymers be exempted from safe materials ("PLC" = polymers of low concern) and materials required for production from PFAS regulations or restrictions on use. Fluoropolymers should be exempt from all regulatory activities under REACH restrictions. Fluoropolymers can be classified as PFAS based on their molecular structure. However, their toxicological and ecotoxicological profile is essentially different from the majority of PFAS substances. Fluoropolymers (= polymers of low concern) that meet OECD standards for PLCs are non-toxic, biologically viable, water-soluble and non-mobilizing molecules, and are judged to have no significant impact on the environment or humans. The stability of fluoropolymers can be directly translated into unique and durable performance characteristics in many applications. Fluoropolymers represent the right foundation for state-of-the-art technology as well as for applications in resin manufacturing and the production of chemical products as we do these innovations are essential. |

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| 4105 | Date:  2023/05/15 09:29  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  TOA INDUSTRIAL CO.,LTD.  Org. country:  Japan  Attachment: | General Comments:  We agree with comment for proposed restriction of PFSA from conference of Fluoro-chemical product Japan. |

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| 4106 | Date:  2023/05/15 09:59  Type:  Individual  Country:  Japan | Answer to specific info request 8:  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. |

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| 4107 | Date:  2023/05/15 10:17  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  FluoroTechnology Co.,Ltd.  Org. country:  Japan  Attachment: | General Comments:  Grease is a lubricating oil of medium to high viscosity.  The composition consists of a base oil and a thickening agent to increase viscosity.  As the base oil, PAO, silicon oil, perfluoropolyether oil, etc. are mainly used. Inorganic particulate matter, PTFE powder, etc. are used as the thickening agent. the base oil of grease does not originally have a very high viscosity , it often happens that only the base oil oozes out of the grease and spreads.  the base oil diffuses, the lubricating performance gradually deteriorates . To prevent this, a fluorinated base oil diffusion inhibitor is added.  By adding a small amount of the fluorine-based base oil diffusion inhibitor to the grease, the outflow of the grease base oil can be prevented. Therefore, in order to maintain long-term lubricity of grease, it is necessary to add a fluorine-based compound.  This function is obtained by the effective action of the fluorine-based oil repellency.  Silicon compounds and the like are conceivable as substitutes, but these substances do not have oil repellency, so satisfactory results cannot be obtained in terms of performance.  compound name oil repellency (hexadecane contact angle) The fluorine compound 69° silicon compound 15° Urethane compound Not measurable (contact angle of 10 degrees or less) acrylic compound Not measurable (contact angle of 10 degrees or less) epoxy compound Not measurable (contact angle of 10 degrees or less) polyethylene Not measurable (contact angle of 10 degrees or less) polypropylene Not measurable (contact angle of 10 degrees or less) ABS Not measurable (contact angle of 10 degrees or less) Nylon 66 Not measurable (contact angle of 10 degrees or less) Polyimide Not measurable (contact angle of 10 degrees or less) polyamide Not measurable (contact angle of 10 degrees or less)               Please also refer to the following patents for these functions.  (Reference Japanese Patents 7072864, 7082811, 7212359) |
| Answer to specific info request 1:  Additive for lubricants , grease. |
| Answer to specific info request 2:  There are no emissions during the manufacturing or usage stages. At the time of disposal, it will be discharged at a level of 10 tons or less per year. |
| Answer to specific info request 3:  If the object used is incinerated or melted, it will decompose and this PFAS will decompose into HF. |
| Answer to specific info request 5:  Since it is an additive, the usage fee is not so much. Based on past performance, it is estimated to be less than 10 tons per year. |
| Answer to specific info request 6:  Refer to attached file. |
| Answer to specific info request 9:  There is no academic information that the substance to be applied for changes into these fluorine compounds. |