**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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| 3932 | Date:  2023/04/26 08:39  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  Printing plate Printing image forming equipment uses PTFE and PFA in the parts that come into contact with the printing plate. The reason for this is to prevent the surface of the printing plate from being scratched by the contacting parts with respect to the coating (printing image formation) surface applied to the printing plate. The use of PTFE and PFA is essential and cannot be replaced. Therefore, please exempt "printing plate printing image forming equipment for printing". |
| Answer to specific info request 1:  5. By way of derogation, paragraphs 1 and 2 shall not apply to: x. [industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiF]; y. [industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiF]; |

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| 3934 | Date:  2023/04/26 14:06  Content:  Scope or restriction option analysis  Baseline  Type:  Individual  Country:  Germany | General Comments:  Dear Madams or Sirs, As can be seen from Table A.1 of Annex A, from my point of view several areas of application of substances containing PFAS are not considered in the present PFAS ban application. I would like to mention the following areas as examples: - the energy sector, especially the production of wind turbines or battery cells - the automotive sector - the mechanical engineering sector - the pharmaceutical sector PFAS-containing materials, substances and intermediate products are used in all these areas. Any substitutes must first be tested for a certain degree of suitability through lengthy trial phases, and I suspect that many substitutes cannot be classified as full substitutes. This reduces the longevity of the products, for example, or increases the maintenance effort. Both of these are detrimental to the environment (green footprint of the products) in my opinion. I am therefore convinced that if a comprehensive PFAS ban is implemented in accordance with the ban proposal, it will no longer be possible to manufacture products in the European economic area with the same properties. This would result in global economic disadvantages for Europe. The ban proposal follows the usual exaggerated "green way of thinking" at the moment and results in the destruction of the economic area of Europe. The rest of the "world economy" will then be happy about the deindustrialized Europe. I therefore call on the responsible bodies to reconsider this ban proposal and also to take into account the economic interests of the companies/manufacturers/large corporations based in Europe. In my view, a deindustrialized Europe cannot be the goal of this legislation. Thanks for your attention. |
| Answer to specific info request 1:  See general comments |
| Answer to specific info request 6:  See general comments |

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| 3935 | Date:  2023/04/26 14:20  Content:  Scope or restriction option analysis  Hazard or exposure  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:  EM-Technik GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  The confidential appendix gives a closer insight in our core business. It contains specific information about EM-Technik GmbH customer groups, products and materials used. A public appendix would lead to business disadvantages, since our competitors and customers are able to receive this confidential information as well. | General Comments:  Consultation EM-Technik GmbH  EM-Technik GmbH is a medium-sizes company with ten subsidiaries abroad, employing 200 people. EM-Technik GmbH is a downstream user - producer of articles. We are using the processes of injection molding, welding and CNC-machining to produce high quality connectors and fittings made of special plastics. Partly in cleanrooms ISO 5 and ISO 7. Our products mainly of Fluoropolymers are widely used handling (connecting, shutting off, regulating, distributing) highly aggressive chemical gases or liquids at a high temperature. Key characteristics valued by our customers are high quality and absolute leak proofness at extreme conditions. For 57 years, 2000 customers worldwide trust in our technology and competences.  Scope or restriction option analysis To start with, EM-Technik GmbH wants to clearly highlight, that our consultation is only concerning the Fluoropolymers. We strongly believe, that Fluoropolymers are a small group of nontoxic chemical compounds which should get exempt of the PFAS proposal of the EU. As it is already indicated in the dossier itself, the nontoxic and non-biodegradable Fluoropolymers are the major fountain of future megatrends, like the green deal, high speed 5G or e-mobility naming only a few of them. Without these materials the leakage of chemicals into the environment and the safety of employees and other people working with these substances could not get guaranteed. Further information in the confidential appendix  Hazard or exposure EM-Technik GmbH collects and recycles all scrap parts and other plastic production waste. The purified regranulate is fed back into the production process to keep our production waste as minimal as possible. Further information in the confidential appendix  Baseline EM-Technik GmbH is using the following Fluoropolymers (annual use stated in the appendix): Polyvinilidene fluoride (PVDF) Polytetrafluoroethylene (PTFE) Perfluoroalkoxy polymer (PFA) In all data sheets the Fluoropolymers are described as: “Not considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments.” (Confidential Appendix 4, Appendix 6, Appendix 7). Our role in the supply chain is: Without our products many industrial sectors would not be able to handle leak free highly aggressive liquids and gases of acids and alkalis safely. Our products are especially designed and manufactured to fulfil these specific needs of the industry. EM-Technik GmbH is involved in several branches and industries, however the major ones using Fluoropolymers are: Semiconductor, Wet chemicals, Chemical industry, Medical industry, Energy sector. Further information in the confidential appendix  Information on alternatives Our products are widely used in applications in the semiconductor production process. The exposure to harsh chemicals, temperature and mechanical strength, limits the use of other materials. Many production standards do not allow metals or other plastics than plastics of high purity like Fluoropolymers. This is stated in: SEMI F57-0622 - (SEMI F57 - Specification for High Purity Polymer Materials and Components Used in Ultrapure Water and Liquid Chemical Distribution Systems). Key characteristics of the products are resistance in high temperatures, high pressures and high chemical resistances. Alternatives for Fluoropolymers such as polypropylene (PP), polyetheretherketon (PEEK) do not fulfil all these special requirements at ones. Therefore, we cannot offer our customers products made of alternative materials without risking tremendous consequences for environment or the health of employees. Further information in the confidential appendix  Information on benefits With the ban of Fluoropolymers, future visions and megatrends such as the energy or traffic transition could not be achieved in Europe. Further information in the confidential appendix  Other socio-economic analysis (SEA) issues EM-Technik GmbH wants to highlight again, that the ban of Fluoropolymers in Europe means a shift of the industries and the applications to other regions of the world. The ban of Fluoropolymers in the EU would lead to major devastation of our company. Further information in the confidential appendix  Transitional period Fluoropolymers and our company as well are part of a complicated, heterogeneous and various supply chain. Since Fluoropolymer products are basically everywhere derogations for special uses or companies are too complex.  Request for exemption EM-Technik GmbH demands a total derogation of Fluoropolymers for the business to business sector. |

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| 3936 | Date:  2023/04/26 15:38  Content:  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  VITLAB GmbH  Org. country:  Germany  Attachment: | General Comments:  The envisaged time of 18 months from EIF will not be sufficient, even if we start already now to convert the entire product range. The qualification of alternative materials for the existing products is complicated and will take a lot of time. Especially because it could be also possible that the existing tools cannot be used with other materials for the manufacture of the products and a new construction will become necessary. We need a transitional period that is extended at least to 6,5 years after entry into force of the restriction for the use of fluoropolymers for the production of special laboratory equipment to be able to find possible alternative materials and to make it possible to produce with them our products. |
| Answer to specific info request 6:  Table A.1 in Annex A of the Annex XV Restriction Report lists in blue highlighted PFAS uses that have not been addressed in further detail, such as laboratory equipment. This includes, in our understanding, all laboratory equipment, e.g. equipment that is used in an analytical laboratory for product analysis in the food industry as well as in the pharmaceutical or petrochemical industry. The equipment is required for reliable examination of product quality and confirmation of product safety. These instruments are also needed to analyse various environmental samples (e.g. soil, water, ...). These can be spectrometers, chromatographs, dosing systems, burettes, pipettes or simply beakers, volumetric flasks, sample vials or tubes. We expressly emphasise that these products are intended for industrial use and have no application in the private environment. a. The laboratory market is a small but important market and has only a minor share of the 840000 tonnes of PFAS that enter the market annually. For our company, we process barely 2 tonnes of the fluoropolymer PFA p.a., which then go to the market as volumetric flasks, beakers and bottles. We cannot provide annual emissions. The waste generated during the manufacturing process is added back to the process directly at the machine, so that almost no plastic waste is produced. The manageable residual quantities go to certified disposal companies. b. The most important functions provided by PFA for the respective application is its high temperature resistance and chemical inertness. The raw material used is also particularly clean and contains no catalyst residues worth mentioning, a basic condition for to production of products for metal trace analysis. c. The number of companies manufacturing these products in the laboratory sector in Europe in particular and throughout the world is very limited. Besides us, there are perhaps less than ten manufacturers of these special laboratory devices in the world. d. There is no alternative material with equally good chemical properties. This is the state of the art and it is very likely that there will no such aquivilant material in future providing the same chemical features. However, there are alternative materials that could be used, but these materials offer poor performance and have a significantly shorter usage periods. When dealing with highly corrosive media, such as concentrated acids (HNO3, H2SO4, ...) or hydrofluoric acid (HF), which are used to digest solid samples, all other materials will quickly be destroyed or cannot be used at all (e.g. glass in the case of HF). The other materials also negatively affect the subsequent analysis due to contamination. This creates the risk of inaccurate analysis and incorrect analysis results. e. As the availability of alternative materials is not yet given and whether and when such a material will be available, it is also not yet possible to estimate whether supply problems with the potential alternative materials could be expected. f. We process currently the available material, which is produced by the chemical fluoropolymer industry. We have no data or indications whether the polymer manufacturers are already researching alternative materials and if and when an alternative could be expected. Therefore, as downstream user, we cannot provide any information regarding the following two points below. i. ii. iii. All currently available materials beside PFA are limited in their functionality and this may cource that users in the pharmaceutical analytical quality laboratory have to change a flask made of other materials more frequently.This will cource significantly higher effort. This is not only leading to increasing costs for analyitics, but also results in much higher amount of waste material. As the determination of specific toxid substances would no longer be possible on todays quality level the comsumer would also be negativly effected due to lower quality of analysis (e.g. toxic substances eating food stuff). iv. We do not have information regarding benefits of alternative providers. g. Commercial impact (no alternative matirial given): The business impact for manufacture (VITLAB) would be -1.500.00 € turnover and five employees. Other manufactures: no information Customers: no information (but noticeable cost increase) |

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| 3937 | Date:  2023/04/27 07:44  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.2. uses: ANNEX XV Conditions of restriction 5 e) ANNEX A.3.3.1.1.Use of PFASs in filtration and separation media CAS RN: raw materials 1189053-60-8 423-39-2 75-38-7 116-14-3 132182-92-4 132182-92-4 1189053-50-6 |
| Answer to specific info request 8:  uses: ANNEX XV Conditions of restriction 5 e) ANNEX A.3.3.1.1.Use of PFASs in filtration and separation media Functions: water and oil repellent, anti-corrosion, HF-resistant coating film. Quantity used: 1-10 t/y Discharge into the environment: no (disposed of as industrial waste or used as a finished product). [Usefulness, benefits] The use of porous filters treated with water and oil repellents offers significant benefits to the social value chain. Fluorinated water and oil repellents (especially fluorotelomer-based) are important application examples due to the unique characteristic origin of fluorine. They are a necessary raw material not only for petrol but also for electric vehicles. [On alternative materials. The evaluation of alternative materials for non-fluorinated water and oil repellents has shown that they cannot fulfil the important performance characteristics derived from the fluorotelomer structure. Currently marketed water and oil repellents for porous filter treatment are time unlimited. [Problems and disadvantages of restricting PFAS Extensive PFAS restrictions (including PFHxA and PFBA restrictions) may have the following consequences. The PFAS regulations are not only a threat to the development of electric vehicles, but also to the development of electric vehicles in general. Significantly reduce the safety and reliability of various components due to much lower performance levels and lifespan. The use of alternative materials will lead to a significant increase in the amount used and an explosive increase in waste. Fluorotelomer, the raw material for fluorinated water and oil repellents, has shown negative results in mutagenicity tests and the proposed restrictions do not immediately apply to handling. [Contents of appeal + p. 11 We request that fluorinated water and oil repellents and fluorotelomer, the raw material for fluorinated water and oil repellents, be exempted from the PFAS regulation as time unlimited uses, recognising that they are widely used in various parts time unlimited for socio-economic activities. |

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| 3938 | Date:  2023/04/27 07:50  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.2. uses: ANNEX A.3.3. Textiles, upholstery, leather, apparel and carpets CAS RN: raw materials 1189053-60-8 423-39-2 75-38-7 116-14-3 132182-92-4 132182-92-4 1189053-50-6 |
| Answer to specific info request 8:  Uses: ANNEX A.3.3. textiles, upholstery, leather, apparel and carpets Function: stain protection. Quantity used: < 1 t/y Emissions into the environment: nil (disposed of as industrial waste or used as a finished product). Usefulness, benefits. The use of fluorine-containing textile treatments for time unlimited workers brings significant benefits to the social value chain. Specific benefits include the provision of stain protection and the ability to maintain performance even after several washes. This leads to less frequent washing, significantly less detergent use and longer fabric life, which is environmentally friendly. Fluorinated textile treatments (especially fluorotelomers) are an important application example due to the unique properties of fluorine. They are special materials that are indispensable for time unlimited worker activities. [About alternative materials]. The evaluation of alternative materials for fluorine-containing textile treatments has shown that they do not fulfil the important performance characteristics derived from the fluorotelomer structure. The currently marketed treatments for fluorinated textiles are time unlimited for time unlimited workers. [Problems and disadvantages of restricting PFAS Extensive PFAS restrictions (including PFHxA and PFBA restrictions) may have the following consequences. ▪ The safety of time unlimited workers is threatened due to much lower performance levels and life expectancy. The use of alternative materials will lead to a significant increase in usage and an explosion of waste. The use of alternative materials will lead to a significant increase in the amount of detergents and other materials used, and a significant increase in the amount of cloth waste. Safety assessment of PFASs. The fluorotelomer used as a raw material for the treatment of fluorinated textiles has shown negative results in mutagenicity tests and the proposed restrictions do not immediately apply to handling. [Contents of appeal + p. 11 We request that fluorotelomer, a raw material for fluorine-containing textile treatments, be exempted from the PFAS regulation as an time unlimited use, in recognition of its demand for time unlimited worker activities. |

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| 3939 | Date:  2023/04/27 07:54  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.11. uses: ANNEX XV Conditions of restriction 5 ee) ANNEX A.3.12. Electronics and semiconductors |
| Answer to specific info request 7:  Uses: ANNEX XV Conditions of restriction 5 ee) ANNEX A.3.12. Electronics and semiconductors Function: water and oil repellent, anti-corrosion, HF-resistant coatings. Quantity used: 1-10 t/y. Use: 1-10 ton/year [Usefulness, advantages] High heat resistance, high chemical resistance, used in semiconductor manufacturing processes. No alternative materials Chlorine-based and hydrocarbon-based oils are not resistant to the reactive etching gases used in semiconductor manufacturing equipment, and cannot be used due to reactions between the waste etching gas and the vacuum pump oil. Problems and disadvantages of restricting PFASs: As mentioned above, alternative materials react with etching gas, resulting in a significant increase in the risk of vacuum pump damage and fire. Safety assessment of PFASs] As PFASs are inert to highly reactive fluorine gas, they have high chemical stability and are considered to have low carcinogenicity as they are negative in the AMES test. The molecular weight is also large (over 1000), so uptake into living organisms is also considered to be low. The substance is considered to be an time unlimited use lubricant and exempt from the PAFS regulation, considering its beneficial effects in the semiconductor manufacturing process. |

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| 3940 | Date:  2023/04/27 08:21  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.14. uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.1.Low viscosity lubricants CAS RN: products 60164-51-4 1198429-15-0 1207376-64-4 428-59-1 |
| Answer to specific info request 8:  Uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.1.Low viscosity lubricants Function: high heat resistance (decomposition temperature > 300°C), high chemical resistance Quantity used: > 100 t/y Environmental emissions: No (disposed of as industrial waste or recovered for reuse). [Usefulness, benefits]. The use of PFPE oil lubricants offers significant benefits to the social value chain. PFPE oil, with its excellent heat and chemical resistance, is an time unlimited lubricant for the semiconductor manufacturing process. The importance of semiconductors as one of the end products goes without saying. Alternative materials. No alternative materials exist. Chlorinated and hydrocarbon-based oils are not resistant to the reactive etching gases used in semiconductor manufacturing equipment and cannot be used because the waste gas, etching gas, reacts with the vacuum pump oil. [Problems and disadvantages of restricting PFAS As mentioned above, alternative materials react with etching gases, significantly increasing the risk of damage to the vacuum pump, risk of fire, etc. Thus, today's socio-economic activities that require semiconductors come to a halt. Safety assessment of PFASs. As they are inert to highly reactive fluorine gas, they have high chemical stability and are considered to have low carcinogenicity as mutagenicity tests are negative. The molecular weight is also large, at more than 1000, so bioaccumulation and uptake in the body are considered low. [Contents of appeal +P11]. Considering its usefulness and importance in the semiconductor manufacturing process, PFPE oil should be considered an time unlimited use as a lubricant and should be exempt from the PAFS regulation. |

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| 3941 | Date:  2023/04/27 08:34  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | Answer to specific info request 1:  sectors: E.2.14. uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.3.Grease |
| Answer to specific info request 8:  Uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.3.Grease Function: High heat resistance (decomposition temperature > 300°C), high chemical resistance. Quantity used: > 100 t/y Environmental emissions: No (disposed of as industrial waste or recovered for reuse). Usefulness, benefits. The use of PFPE oil as a base oil for greases brings significant benefits to the social value chain. PFPE oil-based greases with excellent heat and chemical resistance are time unlimited for the semiconductor manufacturing process. The importance of semiconductors as one of the end products goes without saying. Alternative materials. No alternative materials exist. If chlorinated or hydrocarbon-based oils are used as base oil, the grease is not resistant to the reactive etching gases used in semiconductor manufacturing equipment, and the grease reacts with the waste gas, etching gas, making it unusable. Problems and disadvantages of restricting PFAS As mentioned above, alternative materials react with etching gases, significantly increasing the risk of equipment damage, fire hazards, etc. Therefore, today's socio-economic activities that require semiconductors come to a halt. Safety assessment of PFASs As they are inert to highly reactive fluorine gas, etc., they have high chemical stability and are considered to have low carcinogenicity as mutagenicity tests are negative. The molecular weight is also large, at more than 1000, so bioaccumulation and uptake in the body are considered low. [Contents of appeal +P11]. Considering the benefit and importance of PFPE oil in the semiconductor manufacturing process, grease with PFPE oil as base oil should be considered as time unlimited use and exempt from the PAFS regulation. |

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| 3942 | Date:  2023/04/27 10:25  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Including market share information | General Comments:  - We would like to exempt Fluoropolymer, a raw material for hollow fiber filtration membranes used in the production process of food products, from this restriction. - Membrane filtration is economical because it does not require large amounts of waste, techniques, or energy like diatomaceous earth, and it can be used to filter food without compromising its flavor. - To maintain the economic viability of the membranes, long-term physical strength and durability against cleaning chemicals are required, and to our knowledge, fluoropolymer is the only polymer that can meet both requirements. In addition, fluoropolymers have a stable structure and are free of decomposition products during use, making them an essential material for safe food production. - Article 68 of REACH says "evaluation may lead to the conclusion that action should be taken under the restriction or authorisation procedures or that risk management action should be considered in the framework of other appropriate legislation". We believe that only those PFAS that are harmful should proceed with restrictions after appropriate evaluation. |
| Answer to specific info request 1:  Industrial food and feed production |
| Answer to specific info request 2:  The percentages of emissions are as follows: - The manufacture phase 0% - The use phase 0% - The end-of-life phase 100% |
| Answer to specific info request 3:  - When iron is melted by the arc heat of an electric furnace (3000-7000 degrees celsius), fluorinated resin is incinerated at the same time. Residue can be recycled into roadbed material. Fluorine dust is recovered as gas and used for steelmaking materials. (See confidential attachment) - In addition, since our products are used only B to B, the products after use can easily be managed as industrial waste under the policy. |
| Answer to specific info request 4:  Information on recycling is answered in question 3. |
| Answer to specific info request 6:  b) - Membrane filtration is economical because it does not require large amounts of waste, techniques, or energy like diatomaceous earth, and it can be used to filter food without compromising its flavor. - To maintain the economic viability of the membranes, long-term physical strength and durability against cleaning chemicals are required, and to our knowledge, fluoropolymer is the only polymer that can meet both requirements. In addition, fluoropolymers have a stable structure and are free of decomposition products during use, making them an essential material for safe food production. - The Fluoropolymer we use is certified by the polymer manufacturer to be free of PFAS and PFOS, which are regulated by the POPs regulation. d) e) - Diatomaceous earth filtration requires calcination prior to use, which is expensive in terms of energy costs, and emits a large amount of CO2 along with it. Because it also impairs the flavor of food, diatomaceous earth is being replaced. - Ceramic membrane filtration requires calcination prior to use, which is expensive in terms of energy costs, and emits a large amount of CO2 along with it. Since the throughput is lower than that of organic membranes, large pumps are required to increase the flow rate, resulting in higher electrical costs. Furthermore, it is not economical because it is prone to root clogging. - Organic membranes are characterized by low energy costs because they do not require sintering and do not impair food flavor, and no technically and economically equivalent alternative methods exist. Furthermore, among the organic films, there are no alternative polymers of fluoropolymer as described in 6.b. (See confidential attachment) f) i, ii There is no technically and economically feasible alternative. f) iii - Diatomaceous earth filtration and ceramic filtration are expensive to operate and manufacture, produce high CO2 emissions, and generate a lot of waste. These methods result in a significant decrease in supply due to lower productivity, leading to higher food production costs and increased CO2 emissions in the EU. - Different filtration methods in the food production process will change the taste and flavor and make it impossible to produce food products. - Using membranes with lower strength increases the frequency of membrane replacement, which reduces food production and raises prices. g) - There is a risk that changes in food production methods will increase production costs and make it impossible to produce foods with the flavors we have come to expect. - Livelihoods of many stakeholders, from farmers of food ingredients to food producers and consumers, will be difficult. Soaring food prices and declining production increase the number of people without access to food and cause social problems. - According to ECHA data, PFAS emissions in food applications are extremely low, less than 1% of total emissions, and have little impact on human health and the environment. It is clear whether this restriction will have a greater impact on society or the environment. |
| Answer to specific info request 7:  - In the case of facilities that manufacture products that are directly ingested by the human body, such as food, there must be no foreign matter or eluted substances. Fluoropolymer is a stable polymer and its degradation products do not leach into food. It can also be cleaned with chemicals and does not disassemble, keeping it safe. -See attached for information on socioeconomic impacts. |
| Answer to specific info request 8:  See question 6 and the confidential attachment. |
| Answer to specific info request 9:  See question 3 for information on recycling |

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| 3943 | Date:  2023/04/27 10:33  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.14. uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.3.Grease CAS RN: raw materials 252237-40-4 25291-17-2 17527-29-6 1189053-50-6 1219035-32-1 13252-13-6 37382-64-2 51798-33-5 163702-08-7 163702-07-6 163702-06-5 163702-05-4 132182-92-4 428-59-1 116-15-4 116-14-3 75-45-6 7594-51-6 1623-05-8 10493-43-3 2070-70-4 30320-29-7 30320-27-5 30320-26-4 1644-10-6 1998-53-4 2062-98-8 2641-34-1 13252-14-7 26131-32-8 14548-74-4 174080-50-3 27639-98-1 131628-36-9 646029-82-5 646029-84-7 646029-85-8 34761-47-2 133609-46-8 13252-15-8 27617-34-1 51798-33-5 850734-65-5 2416268-96-5 25038-02-2 204270-10-0 |
| Answer to specific info request 8:  sectors: E.2.14 uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.10.Properties of PFAS-based lubricants and specific properties CAS RN: products 2043-47-2 52591-27-2 1799-84-4 647-42-7 17527-29-6 2144-53-8 125660-00-6 647-42-7 19430-93-4 25291-17-2 80793-18-6 252237-40-4 1189053-50-6 1189053-60-8 1219035-32-1 raw materials 252237-40-4 25291-17-2 17527-29-6 1189053-50-6 1219035-32-1 2062-98-8 13252-13-6 37382-64-2 51798-33-5 163702-08-7 163702-07-6 163702-06-5 163702-05-4 132182-92-4 402-31-3 433-19-2 1189053-60-8 423-39-2 75-38-7 116-14-3 132182-92-4 |

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| 3944 | Date:  2023/04/27 10:40  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.14 uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.10.Properties of PFAS-based lubricants and specific properties CAS RN: products 2043-47-2 52591-27-2 1799-84-4 647-42-7 17527-29-6 2144-53-8 125660-00-6 647-42-7 19430-93-4 25291-17-2 80793-18-6 252237-40-4 1189053-50-6 1189053-60-8 1219035-32-1 raw materials 252237-40-4 25291-17-2 17527-29-6 1189053-50-6 1219035-32-1 2062-98-8 13252-13-6 37382-64-2 51798-33-5 163702-08-7 163702-07-6 163702-06-5 163702-05-4 132182-92-4 402-31-3 433-19-2 1189053-60-8 423-39-2 75-38-7 116-14-3 132182-92-4 |
| Answer to specific info request 8:  Uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.10.Properties of PFAS-based lubricants and specific properties Function: adhesion to metal surfaces and imparting of fluorine properties (corrosion protection, stain protection, water and oil repellency). Quantity used: 10-100 t/y. Environmental emissions: No (disposed of as industrial waste). Usefulness, advantages. The use of fluorinated coatings offers significant benefits to the social value chain. Fluorinated coatings (especially fluorotelomer-based) are important application examples due to the unique characteristics of fluorine. They are indispensable industrial materials/sub-materials for electronics, automotive equipment, etc. Fluorine materials are characterised by their high cost, but the fact that they can be used in small quantities to great effect. Fluorochemical technology is considered time unlimited for the global environment, as it allows solutions to be achieved with very small quantities of chemical substances. Alternative materials. It is also important for electronic and semiconductor materials, which are indispensable for the advanced information society expected in the future. Non-fluorine coating agents, especially silicone-based coating agents, cannot be used for these materials due to their electrical properties. In addition, non-fluorinated release agents do not meet performance requirements at all, making the production of many semiconductor components difficult. Evaluation of alternative materials for fluorinated coatings has shown that they cannot fulfil the important performance characteristics derived from the fluorotelomer structure. The fluorinated coatings currently on the market are time unlimited for industrial applications. [Problems and disadvantages of restricting PFAS Extensive PFAS restrictions (including PFHxA and PFBA restrictions) may have the following consequences. Unacceptable worsening of production costs due to the use of alternative materials due to significantly inferior performance levels and service life. The use of alternative materials may lead to a significant increase in the amount of material used, which may have an impact on human health and the environment. Safety assessment of PFASs The fluorotelomer used as a raw material for fluorinated coatings has shown negative results in mutagenicity tests and the proposed restrictions do not immediately apply to its handling. [Contents of appeal + p. 11] With regard to fluorinated coatings and fluorotelomer, the raw material for fluorinated coatings, we request that they be exempted from the PFAS regulation as an time unlimited use in recognition of their importance in electronic and semiconductor materials. |

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| 3945 | Date:  2023/04/27 10:46  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.1. uses: ANNEX A.2.1. PFASs manufacture - Appendices to Annex A - Appendix A.2. Manufacture, import and uses CAS RN: products 428-59-1 116-15-4 116-14-3 75-45-6 |
| Answer to specific info request 8:  Uses: ANNEX A.2.1. manufacture of PFASs - Appendix to Annex A - Appendix A.2. manufacture, import and uses Function: to provide high heat resistance, high chemical resistance, water and oil repellency and corrosion protection. Quantity used: 500-1000 t/y. Environmental emissions: no (disposed of as industrial waste or used as a finished product). [Usefulness, benefits] Fluoroethers. They are raw materials that can impart functions to fluorine materials, and the performance of the fluorine materials using these functions can bring significant benefits to the social value chain. Fluoroethers are important raw materials that, due to their perfluoroalkyl groups, can exhibit unique features that cannot be replaced by other materials. The presence of ether groups in between the perfluoroalkyl groups gives them low crystallinity, flexibility and cold resistance. They are indispensable raw materials for the performance of special materials (fluoropolymers, FFKM, FKM and coatings). Numerous public comments on the importance of those special materials can be found in. [On alternative materials. The evaluation of non-fluorinated alternative materials has shown that the production of special materials is technically challenging. They are time unlimited raw materials for the performance of special materials (fluoropolymers, FFKM, FKM, coatings, etc.) that are currently on the market. [Problems and disadvantages of restricting PFAS Extensive PFAS restrictions (including PFHxA and PFBA restrictions) may result in. ▪ Difficulties in manufacturing and maintaining the performance of special materials. The impact on sectors supported by special materials (social infrastructure, semiconductors, automobiles, ships, aerospace, medicine, defence, etc.) will be enormous. The safety of people's lives and the information society will be threatened by the use of alternative materials with significantly inferior performance. (Basically, there are no alternative materials.) Alternative materials with significantly inferior performance lead to an extraordinary increase in the frequency of maintenance, resulting in a serious increase in waste. Safety assessment of PFASs. Fluoroether monomers themselves have shown negative results in mutagenicity tests and the proposed restrictions do not immediately apply to handling. The downstream products using them are not likely to be released into the environment if they are handled using appropriate protective equipment and if their life cycles are properly managed. [Contents of appeal + p.11]. Fluoroethers are low-molecular-weight fluorine compounds that are used as raw materials and are widely used in various fields time unlimited for socio-economic activities, and the monomers themselves are not released into the environment, Basically, like R22, as was the case with the ozone regulation, its intended use as a chemical raw material should be permitted and it should not be subject to PFAS regulation in the first place. The applications that are discharging into the environment should be carefully investigated and regulations should be sought for that part. Perfluoroalkyl materials, including PFOA, are referred to as eternal compounds, but with the development of technology, methods other than combustion have been found to decompose them. Regulations that ignore this will have a negative impact on the future development of science and technology, as well as on the development of mankind. The bioaccumulation potential of low molecular weight fluorinated polyethers themselves has not been confirmed, but it is generally accepted that they do not accumulate above a molecular weight of 1000, so substances with a molecular weight higher than that, like polymers, are of low concern and should not be regulated. |

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| 3946 | Date:  2023/04/27 10:54  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.1. uses: ANNEX XV Conditions of restriction 5 a) ANNEX A.2.1.5.1.Polymerisation aid CAS RN: raw materials 252237-40-4 25291-17-2 17527-29-6 1189053-50-6 1219035-32-1 13252-13-6 37382-64-2 51798-33-5 163702-08-7 163702-07-6 163702-06-5 163702-05-4 132182-92-4 428-59-1 116-15-4 116-14-3 75-45-6 7594-51-6 1623-05-8 10493-43-3 30320-29-7 30320-27-5 30320-26-4 1644-10-6 1998-53-4 2062-98-8 2641-34-1 13252-14-7 26131-32-8 14548-74-4 174080-50-3 27639-98-1 131628-36-9 646029-82-5 646029-84-7 646029-85-8 34761-47-2 133609-46-8 13252-15-8 27617-34-1 51798-33-5 850734-65-5 2416268-96-5 25038-02-2 204270-10-0 85737-06-0 120903-40-4 283593-02-2　 178200-05-0 1187-93-5 2070-70-4 1584-03-8 124709-43-9 360-53-2 37881-252237-40-4 25291-17-2 17527-29-6 1189053-50-6 1219035-32-1 13252-13-6 37382-64-2 51798-33-5 163702-08-7 163702-07-6 163702-06-5 163702-05-4 132182-92-4 428-59-1 116-15-4 116-14-3 75-45-6 7594-51-6 1623-05-8 10493-43-3 30320-29-7 30320-27-5 30320-26-4 1644-10-6 1998-53-4 2062-98-8 2641-34-1 13252-14-7 26131-32-8 14548-74-4 174080-50-3 27639-98-1 131628-36-9 646029-82-5 646029-84-7 646029-85-8 34761-47-2 133609-46-8 13252-15-8 27617-34-1 51798-33-5 850734-65-5 2416268-96-5 25038-02-2 204270-10-0 85737-06-0 120903-40-4 283593-02-2　 178200-05-0 1187-93-5 2070-70-4 1584-03-8 124709-43-9 360-53-2 37881-62-2 376-53-4 3107-98-0 13140-21-1 |
| Answer to specific info request 8:  Uses: ANNEX XV Conditions of restriction 5 a) ANNEX A.2.1.5.1.Polymerisation aid Function: surfactant Amount used: 10-100 t/y Discharge into the environment: No (disposed of as industrial waste). Usefulness, benefits. The use of surfactants brings significant benefits to the social value chain. Fluorinated surfactants are an important example of applications derived from the unique characteristics of fluorine. They are indispensable raw materials for the production of special materials (fluoropolymers, FFKM, FKM, etc.). See numerous public comments on the importance of those special materials. If restrictions are to be set, the toxicity, etc. based on scientific findings should be clearly stated and emission standards should be set, without which restrictions are wildly logical. Surfactants in products are also incorporated into the product itself and should be judged with the product's life cycle. (If the product is treated by combustion, there is no release into the environment.) [On alternative materials]. The evaluation of alternative materials for non-fluorinated surfactants showed that it is technically difficult to manufacture special materials. Fluorinated surfactants currently on the market are time unlimited for the manufacture of special materials (fluoropolymers, FFKM, FKM, etc.). [Problems and disadvantages of restricting PFAS Extensive PFAS restrictions (including PFHxA and PFBA restrictions) may have the following consequences. ▪ It will be difficult to manufacture special materials. The impact on sectors supported by special materials (social infrastructure, semiconductors, automobiles, ships, aerospace, medicine, defence, etc.) will be enormous. The safety of people's lives and the information society will be threatened by the use of alternative materials with significantly inferior performance. The use of alternative materials with significantly inferior performance leads to an extraordinary increase in the frequency of maintenance and, consequently, a serious increase in waste. Safety assessment of PFASs. Fluorosurfactants and their raw materials, low-molecular-weight fluorine compounds, have shown negative results in mutagenicity tests and are not immediately subject to the proposed restrictions in handling. [Contents of appeal + p11 With regard to fluorosurfactants and low-molecular-weight fluorine compounds that are their raw materials, we request that they be exempted from the PFAS regulation as time unlimited uses, recognising that they are widely used in various fields time unlimited for socio-economic activities. |

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| 3947 | Date:  2023/04/27 11:14  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Taiyo Manufacturing Co., Ltd.  Org. country:  Japan | General Comments:  While we understand the concern regarding the so called 'forever chemicals', we would consider positive to determine which chemicals included in PFAS are considered substances of high concern.  We are a manufacturer of plastic plated products and a small amount of our processes have chemicals with PFAS, such as mist suppressants for chromic acid etching processes and preliminary surface treatment. Trials were performed in the past using PFAS free chemicals for preliminary surface treatment and their performance was not up to par. As for chromic acid etching, at the moment there is not a single PFAS free mist suppressant in the market. Without the necessary chemicals, our defect rates would increase noticeably, thus causing an considerable economic impact in our company and other enterprises in the same industry. It has to be considered too that defective products can be recycled at a certain extent. However, non-recyclable materials are a burden to the environment. Producing massive amounts of waste in order to get rid of a minimum amount of chemicals is not likely to solve the environmental issue but to worsen it.  It is for the previously stated reasons that we would request a thorough description of those chemicals in PFAS whose usage should be restricted and not to apply the restriction generally until there are feasible solutions. We agree progress and a better environment are for the better but not at just any cost. |

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| 3949 | Date:  2023/04/27 12:22  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Contains technical infomation | General Comments:  ・Ion exchange membranes containing perfluorosulphonic acid polymers, perfluorocarboxylic acid polymers and PTFE reinforcing core material used in the electrolysis process of alkali chloride electrolysis should be excluded from this restriction. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. In addition, caustic soda and chlorine produced by the ion-exchange membrane method play an important role as basic raw materials in various industries and are indispensable chemical products in people's lives. ・Ion exchange membranes are exposed to chlorine, 32% NaOH, hypochlorous acid, and hydrochloric acid at temperatures close to 90°C.No materials are known to be resistant to these substances, with the exception of fluoropolymers. |
| Answer to specific info request 2:  a ・Emissions are 0% during the manufacture and the use phase. ・Emissions are 100% at the end of life phase. |
| Answer to specific info request 3:  ・When iron is melted by the arc heat of an electric furnace (3000-7000°C), fluorinated resin is incinerated at the same time. Residue can be recycled into roadbed material. Fluorine dust is recovered as gas and used for steelmaking materials. |
| Answer to specific info request 6:  a ・Approximate amount of PFAS used in alkaline chloride electrolysis applications : approx. 30-35 tonnes/year ・Type：Chemical industry　 b ・Chemical resistance, ・Mechanical strength c ・Number of Ion-exchange membrane method of alkali chloride electrolysis in EU: 40 companies, 59 factories d ・Ion exchange membranes are exposed to chlorine, 32% NaOH, hypochlorous acid, and hydrochloric acid at temperatures close to 90°C. No materials are known to be resistant to these substances, with the exception of fluoropolymers. e ・As far as the patent literature is searched, no information on consideration of alternatives has been found. f ⅲ ・No material with equivalent performance currently exists. ・Alkali chloride electrolysis methods include the ion-exchange membrane method, the mercury method, which uses toxic mercury, and the diaphragm method, which uses asbestos. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. g ・In the EU, 84.5% of chlorine and caustic soda is produced using ion exchange membrane processes, and if fluorinated resins are no longer available due to PFAS regulations, the majority of chlorine and caustic soda in Europe will not be supplied. ・Caustic soda is an essential substance in people's lives, as it is used in the production of various chemicals as intermediate raw materials and in the manufacture of various industrial and daily end products. ・Chlorine is used in the manufacture of vinyl chloride resin, urethane resin, epoxy resin, synthetic rubber and various solvents. It is also used in the sterilisation of tap water and in the manufacture of pharmaceuticals, making it an indispensable substance in our daily lives. |
| Answer to specific info request 9:  ・Efficient fluoride recovery from poly(vinylidene fluoride), poly(vinylidene fluoride-co-hexafluoropropylene) copolymer and poly(ethylene-co-tetrafluoroethylene) copolymer using superheated water with alkaline reagent. https://www.sciencedirect.com/science/article/pii/S0014305722007285 |

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| 3950 | Date:  2023/04/27 12:31  Content:  Information on alternatives  Request for exemption  Type:  Individual  Country:  Germany  Attachment:  <redacted> | Answer to specific info request 1:  Manufacturing and using of machinery |

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| 3951 | Date:  2023/04/27 12:36  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Contains technical infomation | General Comments:  ・PFA hoses and PFA tubes, PTFE repair tapes and valves containing PTFE used in the electrolysis process of alkali chloride electrolysis should be excluded from this restriction. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. In addition, caustic soda and chlorine produced by the ion-exchange membrane method play an important role as basic raw materials in various industries and are indispensable chemical products in people's lives. ・Hoses, tubes, repair tapes and valves come into contact with chlorine and 32% NaOH at temperatures close to 90°C. No materials are known to be resistant to these substances, with the exception of fluoropolymers. |
| Answer to specific info request 2:  a. ・Emissions are 0% during the manufacture and the use phase. ・Emissions are 100% at the end of life phase. |
| Answer to specific info request 3:  ・When iron is melted by the arc heat of an electric furnace (3000-7000°C), fluorinated resin is incinerated at the same time. Residue can be recycled into roadbed material. Fluorine dust is recovered as gas and used for steelmaking materials. |
| Answer to specific info request 6:  a. ・Approximate amount of PFAS used in alkaline chloride electrolysis applications : approx. 3-4 tonnes/year ・Type：Chemical industry　 b. ・Chemical resistance ・Mechanical strength c. ・Number of Ion-exchange membrane method of alkali chloride electrolysis in EU: 40 companies, 59 factories d. ・Hoses, tubes, repair tapes and valves come into contact with chlorine and 32% NaOH at temperatures close to 90°C. No materials are known to be resistant to these substances, with the exception of fluoropolymers. f. ・No material with equivalent performance currently exists. ・Alkali chloride electrolysis methods include the ion-exchange membrane method, the mercury method, which uses toxic mercury, and the diaphragm method, which uses asbestos. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. g. ・In the EU, 84.5% of chlorine and caustic soda is produced using ion exchange membrane processes, and if fluorinated resins are no longer available due to PFAS regulations, the majority of chlorine and caustic soda in Europe will not be supplied. ・Caustic soda is an essential substance in people's lives, as it is used in the production of various chemicals as intermediate raw materials and in the manufacture of various industrial and daily end products. ・Chlorine is used in the manufacture of vinyl chloride resin, urethane resin, epoxy resin, synthetic rubber and various solvents. It is also used in the sterilisation of tap water and in the manufacture of pharmaceuticals, making it an indispensable substance in our daily lives. |
| Answer to specific info request 9:  ・Efficient fluoride recovery from poly(vinylidene fluoride), poly(vinylidene fluoride-co-hexafluoropropylene) copolymer and poly(ethylene-co-tetrafluoroethylene) copolymer using superheated water with alkaline reagent. https://www.sciencedirect.com/science/article/pii/S0014305722007285 |

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| 3952 | Date:  2023/04/27 12:55  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Contains technical information. | General Comments:  ・Cell gaskets containing PTFE for reinforcement and PVdF reinforcing core material used in the electrolysis process of alkali chloride electrolysis should be excluded from this restriction. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. In addition, caustic soda and chlorine produced by the ion-exchange membrane method play an important role as basic raw materials in various industries and are indispensable chemical products in people's lives. ・Cell gaskets come into contact with chlorine, 32% NaOH and hypochlorous acid at temperatures close to 90°C. No materials are known to be resistant to these substances, with the exception of fluoropolymers. |
| Answer to specific info request 2:  a. ・Emissions are 0% during the manufacture and the use phase. ・Emissions are 100% at the end of life phase. |
| Answer to specific info request 3:  When iron is melted by the arc heat of an electric furnace (3000-7000°C), fluorinated resin is incinerated at the same time. Residue can be recycled into roadbed material. Fluorine dust is recovered as gas and used for steelmaking materials. |
| Answer to specific info request 6:  a. ・Approximate amount of PFAS used in alkaline chloride electrolysis applications : approx. 2-3 tonnes/year ・Type：Chemical industry b. ・Chemical resistance ・Mechanical strength c. ・Number of Ion-exchange membrane method of alkali chloride electrolysis in EU: 40 companies, 59 factories d. ・Cell gaskets come into contact with chlorine, 32% NaOH and hypochlorous acid at temperatures close to 90°C. No materials are known to be resistant to these substances, with the exception of fluoropolymers. f ⅲ ・No material with equivalent performance currently exists. ・Alkali chloride electrolysis methods include the ion-exchange membrane method, the mercury method, which uses toxic mercury, and the diaphragm method, which uses asbestos. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. g. ・In the EU, 84.5% of chlorine and caustic soda is produced using ion exchange membrane processes, and if fluorinated resins are no longer available due to PFAS regulations, the majority of chlorine and caustic soda in Europe will not be supplied. ・Caustic soda is an essential substance in people's lives, as it is used in the production of various chemicals as intermediate raw materials and in the manufacture of various industrial and daily end products. ・Chlorine is used in the manufacture of vinyl chloride resin, urethane resin, epoxy resin, synthetic rubber and various solvents. It is also used in the sterilisation of tap water and in the manufacture of pharmaceuticals, making it an indispensable substance in our daily lives. |
| Answer to specific info request 9:  ・Efficient fluoride recovery from poly(vinylidene fluoride), poly(vinylidene fluoride-co-hexafluoropropylene) copolymer and poly(ethylene-co-tetrafluoroethylene) copolymer using superheated water with alkaline reagent. https://www.sciencedirect.com/science/article/pii/S0014305722007285 |

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| 3953 | Date:  2023/04/27 13:05  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Contains technical information | General Comments:  ・Hose gaskets containing PTFE for reinforcement used in the electrolysis process of alkali chloride electrolysis should be excluded from this restriction. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. In addition, caustic soda and chlorine produced by the ion-exchange membrane method play an important role as basic raw materials in various industries and are indispensable chemical products in people's lives. ・Hose gaskets come into contact with chlorine and 32% NaOH at temperatures close to 90°C. No materials are known to be resistant to these substances, with the exception of fluoropolymers. |
| Answer to specific info request 2:  ・Emissions are 0% during the manufacture and the use phase. ・Emissions are 100% at the end of life phase. |
| Answer to specific info request 3:  ・When iron is melted by the arc heat of an electric furnace (3000-7000°C), fluorinated resin is incinerated at the same time. Residue can be recycled into roadbed material. Fluorine dust is recovered as gas and used for steelmaking materials. |
| Answer to specific info request 6:  a. ・Approximate amount of PTFE used in alkaline chloride electrolysis applications : less than 1 ton/year ・Type：Chemical industry　 b. ・Chemical resistance ・Mechanical strength c. ・Number of Ion-exchange membrane method of alkali chloride electrolysis in EU: 40 companies, 59 factories d. ・Hose gaskets come into contact with chlorine and 32% NaOH at temperatures close to 90°C. No materials are known to be resistant to these substances, with the exception of fluoropolymers. f ⅲ ・No material with equivalent performance currently exists. ・Alkali chloride electrolysis methods include the ion-exchange membrane method, the mercury method, which uses toxic mercury, and the diaphragm method, which uses asbestos. ・The ion-exchange membrane method is an excellent production method with higher energy efficiency and lower environmental impact than other diaphragm and mercury methods. g. ・In the EU, 84.5% of chlorine and caustic soda is produced using ion exchange membrane processes, and if fluorinated resins are no longer available due to PFAS regulations, the majority of chlorine and caustic soda in Europe will not be supplied. ・Caustic soda is an essential substance in people's lives, as it is used in the production of various chemicals as intermediate raw materials and in the manufacture of various industrial and daily end products. ・Chlorine is used in the manufacture of vinyl chloride resin, urethane resin, epoxy resin, synthetic rubber and various solvents. It is also used in the sterilisation of tap water and in the manufacture of pharmaceuticals, making it an indispensable substance in our daily lives. |
| Answer to specific info request 9:  ・Efficient fluoride recovery from poly(vinylidene fluoride), poly(vinylidene fluoride-co-hexafluoropropylene) copolymer and poly(ethylene-co-tetrafluoroethylene) copolymer using superheated water with alkaline reagent. https://www.sciencedirect.com/science/article/pii/S0014305722007285 |

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| 3954 | Date:  2023/04/27 16:21  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  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:  We have included market information, where it would be a disadvantage if our competitors and suppliers receive the information. | General Comments:  In a modern chemical industry, it is necessary to transport chemical safely from the point of manufacturing to the point of use. This can be done by trucks, various types of containers (including ISO-Containers) and also in tanks onboard of ships. Depending on the chemicals that need to be transported, different types of tanks are used, such as steel tanks, FRP tanks, rubber lined tanks or tanks lines with polyethylene on the inside. However, these tanks are not corrosion resistant for all types of chemicals, thus for the harshest chemicals (e.g. highly concentrated sulfuric acid, hydrofluoric acid, sodium hydroxide, …) fluoropolymer linings made from PVDF, ECTFE, FEP and PFA are commonly used. The fluoropolymer lining additionally ensure that the tanks are easy to clean (non-sticking properties) and that the transported chemicals are not contaminated during transport (fluoropolymers are essential when electronic grade chemicals for the production of computer chips are transported).  When it comes to the chemicals industry, fluoropolymers allow for the safe production, storage, handling and use of chemicals through protective equipment and linings. Their chemical stability allows them to be resistant to some of the most corrosive substances on the market and as a result protecting works and equipment from harm.  Production, storage, transport an 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 using the safest and best materials on the market is essential for today’s worldwide chemical industry.  We request full exemption of fluoropolymers from the restriction proposal.  In our view, the Annex XV restriction report does not cover relevant and essential uses of fluoropolymers in the critical sector “Transportation”: Trucks, Containers and Ships carrying the harshest chemicals need to have tanks lined with fluoropolymers for corrosion protection.  Fluoropolymers meet the OECD’s key internationally recognized safety criteria identifying them as polymers of low concern: They are not toxic and not mobile; they do not dissolve in water or contaminate water and they can not enter or accumulate in a person’s bloodstream. They do not present significant toxicity concerns and not degrade into other PFAS (see link: New Study Demonstrates Vast Majority of Commercial Fluoropolymers Meet Criteria for Polymers of Low Concern Designation (americanchemistry.com)  Fluoropolymers are quite expensive. Thus, they are only used in applications where no other products/materials provide a feasible solution. Their chemical inertness and resistance to harsh conditions, corrosion and extreme temperatures (hot and cold), are unique properties, needed in a wide range of applications. The assessment of alternative materials has shown that, when available, they frequently cannot meet the critical performance characteristics of fluorinated materials and are not safer.  Using fluoropolymer is generating significant benefits along the value chain, making them critical in numerous technologies, industrial processes, and everyday products. Banning Fluoropolymers will contradicts the European Green Deal and European Chips Act. The dependency of Europe from products manufactured in other parts of the world is expected to increase in case fluoropolymers are no longer available. |
| Answer to specific info request 1:  The specific use of “fluoropolymers used for lining of tanks to transport chemicals (trucks, containers ships)” is not listed in Table 9.R02 of Annex XV. |
| Answer to specific info request 2:  Depending on the chemicals, their temperature and concentration, the corrosion protective lining is selected. Either PVDF, ECTFE, FEP or PFA is used with thickness typically ranging from 2 mm up to 5 mm. Additionally accessories like welding rod, pipes, fittings and stock shapes are need. The larger volume of fluoropolymers used in our company is already produced without the use of fluorinated polymerization aids. To further reduce the risk of emitting small molecular PFAS from the fluoropolymers, most of our suppliers have already announced that they will change their production process to non-fluorinated polymerization aids in the future. Our company plans to use polymers produced with non-fluorinated polymerization aids as soon as they become available. 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 expected to be HF, also some small molecular PFAS are expected to emit. 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. We are committed to implement an emission control strategy to detect PFAS emission and to capture them during processing. We have state of the art technologies in place to avoid loss of fluoropolymer during the production our facility. We capture and recover fluoropolymer waste during manufacturing in processing for recycling. In case recycling is not possible the fluoropolymer-waste is fed into the waste stream in line with current laws and regulations. Incineration is said to effectively destroy PFAS if temperatures are above 850 °C. Storage and handling Proper Packaging avoids PFAS loss during the transportation and storage. After production, products are packed and stored properly. The use-phase: Sheets made from fluoropolymers are used for the lining of tanks in trucks and ships as well as used for lining ISO Containers. It must also be considered that fluoropolymer is on the inside of the tank only. During the use phase at ambient temperatures, emissions from PVDF, ECTFE, FEP and PFA do not occur (below detection limit), because the material is extremely stable, inert and does not degrade into small molecular substances over the whole life-time. End-of-life: Equipment which is decommissioned after service life (~10-20 years depending on the application) can be collected and deposited or incinerated according to the state of the art and in line with laws and regulations. |
| Answer to specific info request 6:  The missing use discussed in this statement is related to the transportation of chemicals, that require specialized corrosion protection layers on the inside of trucks, containers and ships in case harsh chemicals are transported. In the past few years in addition to trailers (for trucks) and containers made from metal, also solutions using FRP were introduced to the market. The advantage is that FRP tanks with an inside lining of thermoplastic material, such as PVDF, ECTFE, FEP and PFA have less weight, thus more payload is possible. Further information about this specific applications and why fluoropolymers have benefits and are in some cases the only solution, can be found in the following information:  See link #1 to website (confidential)  See link #2 to website (confidential)  See annex 1: L. Djukic, Specialized dangerous goods tanks for the transport of highly corrosive chemicals, JEC Composites Magazine, Nr. 107, Aug-Sep. 2016  See annex 2: A. Ushakov, Composites tank container for multimodal transportation system, JEC Composites Magazine, Nr. 107, Aug-Sep. 2016  See annex 3, 4, 5 and 6: various successful project descriptions  See annex 7: Application Spotlight: Tank Liners, Arkema, January 2020 b. The key functionalities provided by PFAS for the relevant use. Various chemical resistance lists (e.g. DVS Codes 2205-1, DIBt Media list, ISO TR 10358) confirm the superior chemical resistance of fluoropolymers against many chemicals. While other materials (e.g. PE, PP, rubber, …) can only handle mild chemicals and lower concentrations, for many applications only the combined properties as exhibited by fluoropolymers enable feasible and economic solutions. Also metals do not show such a universal chemical resistance, at least not in cost effective way: • Outstanding chemical resistance to a broad range of chemicals from -200 °C up to 260 °C (e.g. H2SO4, NaOH, HNO3, HF, HCl, NaOCl, …) • Easy installation inside of tanks and leak tight welding lead to high safety and long life-times. • Fluoropolymer linings offers simple repair options since the sheet can be welded again after proper preparation in the case of mechanical or thermal damages. • Easy to clean (very small amount of residues remain in the tank after draining) due to not sticking properties because of very low surface tension. Less water is needed for cleaning. And cross contamination in case different chemicals are transporter are reduced to a minimum. • Extremely low leach-out of fluoropolymer lining does not contaminate high purity chemicals during transport (essential for semiconductor industry) and in compliance with Semi F40, Semi F57 and Semi C90, etc. • Toughness of the fluoropolymer ensure high safety, even in the case of accidents. • Flame resistance (UL94 classification V0) • Physiological non toxic One must consider that fluoropolymer are a quite costly solution. Thus, fluoropolymers are only used in applications where no alternatives exist or where alternatives are extremely costly. c. The number of companies in the sector estimated to be affected by the restriction. Apart from our suppliers for ECTFE (Solvay), our company and our competitors, also the entire downstream value chain will be effected in case fluoropolymers are banned. 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. Where alternatives to fluoropolymers are available, they are already used today because fluoropolymers are high priced. Thus, for harsh chemical environments it will extremely difficult to develop alternatives. Especially if you want to use the tank for transporting chemicals for different chemicals. Also impossible is to substitute tanks that are used for electronic grade chemicals. These specialized chemicals are needed in semiconductor industry in a very pure form and if they are in contact with metals the chemicals will be contaminated with metal ions. Test for leach out from metals to ultra-pure chemicals are standardized in SEMI F40, SEMI F57 and SEMI C90. Furthermore, semicon production companies have a stringent copy exact process. Using tanks without fluoropolymers could jeopardize the production yield of computer chips, thus any changes in the supply chain are evaluated and need to be approved. Availability: - Various Steel compositions (stainless steel, high-alloy steel like nickel-alloy, titanium alloy, hastelloy, special grade steel…) o The chemical resistance, availability, cost-benefit ratio is much poorer as compared to fluoropolymers o For example: The chemical resistance of selected fluorpolymers is better in the long term, compared to most of the available steel compositions o For specific applications, steel equipment can be used, with reduced life time and less safety. o For the stated chemicals, fluorpolymers are offering significantly longer service times and safety compare to steel grades: Hydrofluoric acid, high concentrated Hydrochloric acid, Sodium-Hypochlorite, Sodium chloride - Other polymers (PE, PP, PVC, FRP, PA) are showing reduced chemical and temperature resistance. Technical and economic feasibility: - Reduced service life and reduced operation safety (z.B. Tabelle Numbers needed, Corrosion Guide) - High-Alloy steels are much more expensive compared to fluopolymer solutions, which will have an direct impact to the price of the down stream users - Processes requiring high purity chemicals can not be performed due to contaminated chemical … - Equipment weight higher CO2 pollution Hazards and risks: - Reduced service life of equipment and plant safety - Environmental food print of steel production: Studie - PVC Bann in Scandinavia 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 employment numbers for the sector. The influence of banning fluoropolymers on transportation of chemicals is difficult to assess. While the impact for our supplier, our company and our customers is not that big looking at the pure numbers, banning fluoropolymers would have a big impact on a vast number of downstream users and in the end also on end user prices. |

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| 3955 | Date:  2023/04/27 17:00  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Austria  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Since we provide detailed market information and information about customers, it is necessary to keep this information convidential. | General Comments:  Why Fluoropolymers for power plants and waste incineration?  The combustion of wastes of diverging qualities or fossil energy sources leads to the formation of gases with a high content of sulfur, chlorine and fluorine compounds. When the dewpoint of these gases is underrun in heat exchangers, housings and ducts in order to re-cycle more heat out of the combustion gases, this leads to a heavy condensation of hydrochloric, hydrofluoric and sulfuric acid on the involved equipment and in consequence to one of the strongest types of corrosion known, called dewpoint corrosion. The latter even corrodes the most resistant steel grades and thus requires other technical solutions. A lining of the condensing heat-exchangers, their housings and the flue gas ducts with the fully-fluorinated thermoplastic PFA (tetrafluoroethylene-perfluoroalkylvinylether) renders possible a service of the heat exchangers under condensing conditions and consequently increases the total power production efficiency of the waste-incineration plant, even having a positive environmental effect due to a positive influence on the overall energy mix. The suitability of this technical principle had already been demonstrated in multiple successful examples in fossil- and waste-fired power plants.  In our view, the Annex XV restriction report does not cover relevant and essential uses of fluoropolymers in the critical sector “chemical industry”: Semi finished products like sheets, welding rods or caps are mechanically solid, chemically resistant and stable even in harsh and corrosive environments |
| Answer to specific info request 1:  The specific Sector “PFA products for Heat Exchangers and ducts of waste incineration and fossil power plants.” is not listed in Annex XV. |
| Answer to specific info request 2:  For the specific use-case mainly PFA products are used. PFA products like foils (thickness of 1.5 mm and 2.3 mm), pipes (from 20 mm up to 110 mm), welding rods and PFA covering caps etc. are solid products. Today most PFA raw materials are produced using fluorinated polymerization aids that may remain in extremely small amounts (ppm) within the PFA 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. For example, Gujarat Fluorochemicals has already announced that by July 2023 they will change their production process to eliminate the need for fluorinated polymerization aids for the production of PFA. We have the goal to use only PFA resins that are produced without fluorinated polymerization aids after 2025. Thus, already today, we are selecting and shifting more and more quantity to PFA suppliers that use the new technology that can produce the PFA without fluorinated polymerization aids.   During manufacturing: From literature it is possible to asses the emissione of fluoropolymers during thermoplastic processing (e.g. extrusion of sheets at 370 °C) as well as at the maximum opperating temperature (260 °C). In the book Technology of Fluoropolymers (Drobny et al. 2009; Link-to-Drobny-2009) presents a study where loss of weight due to thermal degradation of PTFE is evaluated. Loss of weight is mainly HF, but also low molecular PFAS could cause the weight loss. One can assume that this findings are also valid for PFA, because PFA has exactly the same molecular structure, the only difference is, that PFA has shorter molecules. Table according to Drobny et al 2009, page 171-172 During the extrusion of sheets, pipes and welding rods, the PFA is heated up to about 370 °C and kept at this temperature for about 10 Minutes, before it is cooled down again. According to Drobny et al, we can calculate the emissions of PFA at the extrusion temperature of 370 °C as follows:  33500 kg \* 0.004 %/h /100 \*10/60 = 0,22 kg Extruding products from about 33500 kg of PFA, is expected to lead to about 0.22 kg of low molecular emissions according to Drobny at al. One should not forget these emission are mainly composed of HF, thus only a fraction of the 0.22 kg/year have the potential to be PFAS. In our facility critical production areas like extruder, extrusion die and calender-rolls are covered with a ventilation hood to suck off possible low molecular substances and HF. The processing gases are afterwards cleaned via a gas scrubber before released into the atmosphere. Measurement show, that low molecular PFAS accumulate in water used in the gas scrubber, thus it is proven that they are removed from the off gases collected above the extrusion line. Precise work and proper work instructions avoid loss of fluoropolymers during production. Material from the starting process as well as chips from cutting are collected and added again to the extrusion process. Material which cannot be processed again is stored in containers and sent for incineration following Austrian laws for handling waste. Storage and handling Proper Packaging avoids PFAS loss during the transportation and storage. After production, products are packed sold in sales units like: • Sheets: 12.5 m² and 25 m² • Pipes: OD 32 – 110 mm; Length = 5 m • Welding Rod 3 -4 mm (1 kg Spool) During the production of semi-finished sheets, we therefore expect no environmental pollution processing the beforementioned Fluoropolymers (no spraying, no microplastics, no ionic or non-ionic PFAS from coatings etc.) The use-phase: Products are used in the following specific sub-uses: • PFA semi-finished products (Foils, welding rod, pipes etc.) are used for the lining of the heat exchanger and plant equipment which are in direct contact with the condensating sulfuric acid (260 °C, 98 % Sulfuric acid) and flue gas. • Semi-finished products are installed in a controlled environment (chemical plant, workshop) which ensures that fluoropolymers are not released into the environment. Unusable cuttings, shavings, etc. are collected and sent for incineration or recycling. During the use phase the PFA is used at a maximum temperature of about 130 - 230 °C. Assuming the worst case of 260 °C, the following emissions can be expected from PFA according to Drobny at all during the lifetime of 15 years:  33500 kg \* 100\*10^-11 %/h /100% \* 24 \* 365 \* 15 = 0.044 kg Considering that this is the worst-case scenario at the topmost application temperature and that not all of the 0.044 kg are PFAS, but mainly HF, the release of PFAS into the environment is negligible during the whole use phase. Additionally, it is expected that the emission are not constant, but are slowly decreasing during the life-time. That the emissions caused by PFA are negligible becomes very obvious when looking at the data presented by ECHA during the webinar on April 5th 2023: Emissions from fluorinated gases, emissions from textiles or emissions from medical devices are expected to be in excess of >>1000 t each year. Thus, restriction need to focus on applications that cause most of the emissions. see Table from ECHA webinar, April 5th 2023 End-of-life: PFA Fix Point lining which is decommissioned after service life (~ 10-years depending on the application) will be deopsited under strict governmental rules (hazardous waste) in dedicated landfills or will be incinerated. PFA Products are stable and will not degrade to small molecular PFAS. |
| Answer to specific info request 6:  The process discussed is handling the corrosion prevention from Heat Exchangers and Flue gas ducts in waste incineration or fossil power plants, which are used in all European countries and also other parts of the world. Due to the increasing environmental regulations the demand of waste incineration plants is constantly growing. By using this heat recovery technology, the plant efficiency can be increased, followed by an reduction of the CO2 emissions, see example from a Heat Recovery system supplier: For example, an 830-MW power plant is able to increase efficiency by approximately 1.4% and reduce CO2 emissions by approximately 100,000 t annually, and save approximately 23 MW of reheating steam. see Literature: Link b. The key functionalities provided by PFAS for the relevant use. Condensing heat exchangers are located after the boiler, air pre-heaters and electrical precipitators. The condensing heat exchangers are furthermore upstream of the flue gas de-sulfurization. Upstream of the condensing heat exchangers the gas temperatures are high and no flue gas condensation occurs. Therefore, metals are the appropriate material for these regions in the flue gas stream. In the flue gas desulfurization section, the flue gases are less corrosive and the gas temperatures lowered to a point, where often cheaper materials like polypropylene (usable to approx. 90°C) can be used. Hence, the usage of PFA linings and condensing heat exchangers is attributed to a particular part in the flue gas stream, where the corrosion is extremely high and the temperatures still too high to use other plastic materials. The publication Fluoroplastics as Corrosion Protection in Flue Gas Desulphurization Units (VGB Power Techn 4/2007, paper attached below) explains why PFA is successfully used in this specific application. • Long term chemical resistance of PFA against condensating sulfuric acid, hydrochloric acid and hydrofluoric acid form on the surface of the heat exchangers and the surrounding equipment o Corrosion Guide II o ISO 10358 o Test report Exposure Testing Swerea Kimab (attached to submission) • A long-term leak proof lining system can be achieved under these critical operation conditions. • The PFA lining offers simple repair options since the sheet can be welded again after proper preparation in the case of mechanical damages. • Increasing the efficiency of the power plant due to an increase in reliability and increased availability (reduced maintenance). • Due to the antistick properties, ash and other particles transported in the flue gas, will not stick to the PFA lining and cleaning of the heat exchanger is easy. An internal test report from a PFA foil used in the incineration plant München Nord for 10 years shows that the PFA foils are in very good condition (slightly reduction of mechanical properties, all other properties are similar to the initial sample) considering the long service life. This report again shows the perfect suitability of PFA foils in this application, see report attached. c. The number of companies in the sector estimated to be affected by the restriction. All operators of waste incineration plants or fossil power plants in Europe that are using a heat recovery system. Based on literature more than 500 waste incineration plants are in operation in Europe in 2020 https://www.cewep.eu/wp-content/uploads/2023/01/EU-Map-2020.pdf 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. The condensation of the acid droplets on the metal surface leads to the so called dew point corrosion. As a result regular steels and stainless steels are destroyed immediately, see literature: [1] Oil & Gas Journal. New correlation predicts dewpoints of acidic combustion gases. 22 February 2010. [2] W. M. M. Huijbregts, R. G. I. Leferink, Anti Corrosion Methods and Materials Volume 51, No 3, (2004), 173-188. [3] David A. Lewandowski. Design of Thermal Oxidation Systems for Volatile Organic Compounds, 1st Edition (2000). CRC Press. ISBN 1-56670-410-3. [4] John J. McKetta. Encyclopedia of Chemical Processing and Design, Volume 61, 1st Edition (1997). CRC Press. ISBN 0-8247-2612-X. [5] W. Cox, W. Huijbregts, R. Leferink, Components Susceptible to Dew-Point Corrosion. ASM Handbook Volume 13C, Corrosion: Environments and Industries (2006). ASM International. 491-496. [6] T. de Weijer, W. Huijbregts. Severe corrosion in a waste incinerator plant due to flue gas and steam leakage. Anti-corrosion methods and Materials Volume 50 (2003). 334-340. [7] D. C. Agarwal and G.K. Grossmann, Case Histories on the Use of Nickel Alloys in Municipal and Hazardous Waste Fueled Facilities. CORROSION. (2001), March 11 - 16, 2001, Houston, Tx. Copyright NACE International. 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 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. PFA lining has become established over the last few years and represents the current state of the art. 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. Our company is not active in metals and ceramics and we do not have the know-how to evaluate possibilities except for polymers. 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 employment numbers for the sector. PFA Foils are an important component of waste incineration plants used the in the heat recovery system of the plant. Due to the increasing environmental regulations the demand of waste incineration plants is constantly growing. By using this heat recovery technology the plant efficiency can be increased, followed by an reduction of the CO2 emissions, see example from a Heat Recovery system sypplier: For example, an 830-MW power plant is able to increase efficiency by approximately 1.4% and reduce CO2 emissions by approximately 100,000 t annually, and save approximately 23 MW of reheating steam.see Literature: Link In Europe 2.5 M tons of residual waste is created per week. This waste can be landfilled or be used via thermal recycling (waste incineration plant) to produce energy and heat. Producing energy from this local residual waste reduces the dependency on fossil fuels (like natural gas import). If the amount of waste were to be landfilled, additional 92 M tonnes of CO2 emissions are be generated, which should be saved to achieve the 2030 green house gas emission target of the EU. Source: CEWEP.eu The effect of banning PFA could have a substantial impact on the whole waste management of the EU, and for sure the European value chain. Additionally there is an impact on the environment possible in case flue gas treatment has to be done with material that have lower performance compared to fluoropolymers. |

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| 3956 | Date:  2023/04/27 17:31  Content:  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Guarnitex Srl  Org. country:  Italy | General Comments:  We produce PTFE thread seal tape and gaskets. If the PFAS restriction goes ahead then 20 employees will lose their jobs at Guarnitex, Credaro, Italy because we work 100% with PTFE and there is no alternative material for production of our tapes & gaskets. Our factory and machinery is totally set up for processing PTFE and is not suitable for processing other materials (cost implication if in future another material was discovered to be suitable). |
| Answer to specific info request 1:  PTFE Thread Sealing Tape; Expanded PTFE Gaskets |
| Answer to specific info request 2:  At end of manufacture of the tapes, our scraps of PTFE tape are sent for recycling at a 3rd party company where they are micronised and used again as an additive in inks, varnishes, coatings and oils. |
| Answer to specific info request 5:  We transform/process 50 tons of PTFE per year. No PFAS emissions data available but comply with all local emissions requirements. |
| Answer to specific info request 6:  30 tons of the total 50 tons of PTFE (per year) goes into gaskets for use in the chemical industry and industrial production sites. This PFAS use appears to be missing. (The thread seal tape use consumes 20 tons of PTFE per year and is already mentioned/listed). |
| Answer to specific info request 7:  There is no alternative to the non-permanent sealing provided by PTFE thread seal tape (paste or liquid provides a permanet seal which is not the same, not always suitable). There is no material available on the market with the high temperature resistance & resistance to highly aggressive chemical solutions/agents that PTFE offers. Other properties not matched by alternative materials are the long service life and long shelf life of PTFE tape. |
| Answer to specific info request 8:  If no alternative material to PTFE is found/identified/invented in the near future, our company will close. 20 people lose their jobs. If an alternative material were to be found, we would have to pay to refit the whole factory/ replace all the processing equipment which may not be viable/possible economically. If PTFE gaskets are no longer available (without alternative) the whole European manufacturing industry would be affected. |

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| 3957 | Date:  2023/04/27 18:44  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Austria  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  We give specific information about customers and the market. This information needs to be treated confidentially so that we do not have negative impact on our business (e.g. from our competitors). | General Comments:  Specific Use case: Sulfuric Acid storage for water treatment on ships  Why Fluoropolymers for sulfuric acid?  Large ships, especially cargo ships for container, oil, ect…. , need to take up water for ballast when they cruse without loads. Releasing the ballast water in different locations than it was taken up, can cause wide-spread environmental damage to coastal ecosystems by invasive aquatic species carried in the ballast tanks of ships. Thus, since few years it is common to treat the ballast water and eliminate the worldwide transfer of invasive species. On 4. March 2023 the United Nations High Seas Treaty was finally signed by 190 member states requiring measures to avoid carrying invasive aquatic species onboard of ships across oceans.  Using sulfuric acid, chlorine dioxide disinfectant is produced on the ships for effectively treating the ballast water during intake (see Link). One key part of the chlorine dioxide production is a storage tank for sulfuric acid. To provide adequate corrosion protection of the H2SO4 tanks, they are lined using ECTFE sheets. The H2SO4 tanks on ships were subjected to a astringent approval process from DNV.  When it comes to safe handling of H2SO4, fluoropolymers like ECTFE provide the most efficient solutions. Production, storage, transport an 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. Fluoropolymers play a key role in this aspect.  We strongly believe that the restriction proposal should differentiate between the various types of PFAS based of their chemical composition, their toxicological profile and the production method (e.g. the production of fluoropolymers without fluorosurfactants) as well as their specific uses. Not all PFAS are the same and there is no scientific basis to regulate them all the same. For detailed scientific information on the safety and environmental profile of fluoropolymers, we suggest to approach Cefic’s FFP4EU or Plastic Europe’s Fluoropolymer Group. Further information can also be found in Henry et al. (2018) and Korzeniowski et al. (2023), as well as in European Commission, Directorate-General for Environment, Bougas, K., Corden, C., Crookes, M., et al. (2020)  We request full exemption of fluoropolymers from the restriction proposal.  The Annex XV restriction report does not cover all relevant and essential uses of fluoropolymers in the critical sector “transportation”: Sulfuric acid storage tanks onboard of ships need to added to Annex XV. |
| Answer to specific info request 1:  The specific use of “fluoropolymers used for lining of H2SO4 tanks onboard of ships”,, which is necessary for the production of water disinfectants to purify ballast water is not listed in Table 9.R02 of Annex XV. |
| Answer to specific info request 2:  For this specific use, currently mainly ECTFE sheets with a thickness of 2.3 mm is used and additionally also ECTFE welding rod, pipes and fittings are needed as accessories. 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 facility. 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: • Sheets: 12.5 m² and 25 m² • Pipes: OD 32 – 110 mm diameter; Length = 5 m • Welding Rod 3 -4 mm diameter (1 kg Spool) During the production of semi-finished sheets, we therefore expect no environmental pollution processing the beforementioned Fluoropolymers. The use-phase: Products are used in the following specific sub-uses: • ECTFE semi-finished products (sheets, welding rod, pipes, fittings etc.) are used for the lining of tanks onboard of ships in a well-controlled environment which ensured that ECTFE is not released into the environment. It must also be considered that ECTFE is on the inside of a steel tank only. During the use phase at ambient temperatures, 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 life-time. End-of-life: Equipment which is decommissioned after service life (~10-15 years depending on the application) could be collected and deposited or incinerated according to the state of the art. There-fore it would be necessary to implement international regulations of dismantling and recycling ships. However, even at the end-of-life ECTFE remains very stable and does not degrade into small molecular PFAS, but it remains inert and is not expected to contaminate the environment. |
| Answer to specific info request 6:  The missing use discussed is related to the transportation industry. On board of large ships, sulfuric acid is need to for producing chlorine dioxide. For the safe and reliable storage of the sulfuric acid, the best solution is to line the tanks with ECTFE sheets for corrosion protection. Onboard of ships the chlorine dioxide is needed for effectively treating the ballast water during intake. By treating the ballast water, it is ensured that invasive spices are not transported across the ocean causing wide-spread harm to costal ecosystems. Thus, today regulations are in place that treatment of ballast water needs to be done. Further information about ballast water treatment onboard of ships can be found on the following website. This specific system is the best technology for large ships. b. The key functionalities provided by PFAS for the relevant use. Various chemical resistance lists (e.g. DVS Codes 2205-1) and the publication “Polymers in sulphuric acid service” (Sulphure Magazine, number 358, May-June 2015) confirm that ECTFE is chemically resistant to sulfuric acid um to 100 %. While other materials (e.g. PE, PP, rubber, …) can only handle lower concentrations. Also metals to not enable such a universal chemical resistance, at least not in cost effective way. • Long term chemical resistance of ECTFE against sulfuric acid (>98 %) at ambient temperatures in the H2SO4 storage tank. • Long-term leak prove lining for steel and FRP tanks • The ECTFE lining offers simple repair options since the sheet can be welded again after proper preparation in the case of mechanical or thermal damages. • Increasing the safety and reliability of the water treatment system on ships c. The number of companies in the sector estimated to be affected by the restriction. Apart from our suppliers for ECTFE (Solvay) and the companies producing the water treatment system, the largest impact is expected for the shipping industry and the companies operating the vessels. 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. It is not our expertise to evaluate alternatives for treating ballast water of ships. There are other systems on the market that do not require sulfuric acid. However, especially for large ships, this specific system that uses sulfuric acid onboard of ships to produce disinfectant has proven to be reliable, most effective in treating the ballast water and also very cost effective. In order to protect the marine environment and avoid the transport of invasive species across oceans, it is essential to keep this systems on the market. Due to the arduous approval process at DNV that is expected to take several years and cost in excess of 1 Mio €, short term, no alternatives are available. f. For cases in which substitution is technically and economically feasible but more time is required to substitute: • 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); • the time required for completing the substitution process (including any relevant certification or regulatory approvals); • 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); • information on the benefits for alternative providers. The steel tank for the sulfuric acid by itself is not resistant and would corrode and leak quickly. Alternatives or the lining would be available but are impacted by the PFAS restriction proposal as well. It would be possible to use PVDF, FEP or also PFA for the internal corrosion protective lining. Using PE or PP would not allow to use sulfuric acid with such a high concentration. Information about the corrosion resistance to sulfuric acid can be found in the attached paper in the Annex (Sulphur Magazine, number 358, May-June 2015). It clearly shows the that fluoropolymers are a superior solution at highly concentrated H2SO4. We assume that it would be possible to use metal that is corrosion resistant to 96 % sulfuric acid. A detailed evaluation is not possible from our side, because metals are not our expertise. In any case, it would significantly increase the cost of the disinfecting system and it would require to start a new approval process. In total we assessed that it could take up 5-7 years to find an alternative for H2SO4 storage tank. 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 employment numbers for the sector. While the impact for our supplier, our company and our customers is not that big looking at the pure numbers, banning ECTFE and other fluoropolymers would increase the cost of water treatment onboard of ships and jeopardize the wellbeing of costal marine environment. The biggest impact is expected for international shipping companies and operators of vessels. In the end the transportation costs of all goods shipped in and out of Europe by sea would increase and impact our cost of living even further (e.g. increased inflation). |

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| 3958 | Date:  2023/04/28 04:23  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties. Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm. 6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.10. uses: ANNEX XV Conditions of restriction 6 o) ANNEX A.3.11.1.2. Sealing applications A.3.2.1.2. Fluoroelastomers\_Table A.13.\_Automotive A.3.2.1.2. Fluoroelastomers\_Table A.13.\_Aerospace A.3.11.1.2. Sealing applications A.3.11.1.3. Combustion engine system A.3.11.2.4. Polymeric PFASs\_Sealing applications A.3.2.1.2. Fluoroelastomers CAS RN: products 9011-17-0 25190-89-0 56357-87-0 26425-79-6 163336-49-0 177484-43-4 raw materials 13252-14-7 1478-61-1 1100-88-5 31206-90-3 83558-87-6 126661-05-0 75768-65-9 |
| Answer to specific info request 7:  uses: ANNEX XV Conditions of restriction 6 o) ANNEX A.3.11.1.2. Sealing applications A.3.2.1.2. Fluoroelastomers\_Table A.13.\_Automotive A.3.2.1.2. Fluoroelastomers\_Table A.13.\_Aerospace A.3.11.1.2. Sealing applications A.3.11.1.3. Combustion engine system A.3.11.2.4. Polymeric PFASs\_Sealing applications A.3.2.1.2. Fluoroelastomers Features: Features by being used as sealant: Heat resistance, cold resistance, wear resistance, shock resistance, chemical resistance, etc. Prevents the outflow of oil and other objects to be sealed. Longer life of parts Heat resistance, cold resistance, wear resistance, impact resistance, chemical resistance, electrical properties, insulation, permeability, weather resistance, ozone resistance, etc. Usage:>100 t/y Emissions to the environment: None (disposed of as industrial waste or used as finished products) 'Usefulness and Benefits of FKM The use of FKM has brought significant benefits to society's value chain. The unique features of FKM can not be realized with other materials. Therefore, the technical feasibility is nil. FKM's unparalleled chemical and heat resistance and unique electrical performance, combined with its stability, provide durable and durable performance in every application, contributing to extended product life. About Alternative Materials Our research into FKM alternatives has shown that materials other than FKM/FFKM often fail to meet the critical performance characteristics of FKM-based materials, and that FKM-based materials often fail to meet multiple characteristics and ranges that are time unlimited for the applications in which they are needed. Problems and Disadvantages of Restricting PFAS Broad PFAS regulations (including PFHxA and PFBA regulations) can result in: Unacceptable deterioration in production costs due to the use of alternative materials due to significantly lower performance levels and longevity. Serious deterioration in product safety. Serious impact on social infrastructure and human life. Negative impact on emerging and growing technology markets such as energy storage, electrification, renewable energy and hydrogen. In addition to the need to redesign products, unacceptable constraints arise on products that must meet stringent standard requirements (e.g., safety standards). Safety evaluation of PFASs FKMs are classified as PFAS1 based solely on their molecular structure. However, their environmental and toxicological assessments clearly differ from the majority of other low-molecular-weight PFASs in the following respects: In general, the properties of many FKMs do not exhibit the environmental and toxicological assessments associated with some PFASs of concern. FKMs are chemically stable, non-toxic, biologically available, non-water-soluble, non-mobile substances that are judged to have no significant impact on the environment and human health. Contents of the appeal We believe that the proposed PFAS REACH regulations should result in the exemption of FKM from any regulatory action under the REACH regulations, recognizing its importance in the safe use and application of FKM by distinguishing diverse PFAS groups according to their respective risk assessments and characteristics. |

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| 3959 | Date:  2023/04/28 05:00  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.9. uses: ANNEX XV No derogation ANNEX A.3.10.1.17. Polymeric PFASs\_Fluoroelastomers Appendix A.3.10. Medical devices Table A.102. Polymers and elastomers used in medical devices (including medical device production) CAS RN: products 9011-17-0 25190-89-0 56357-87-0 26425-79-6 163336-49-0 177484-43-4 raw materials 13252-14-7 |
| Answer to specific info request 8:  uses: ANNEX XV No derogation ANNEX A.3.10.1.17. Polymeric PFASs\_Fluoroelastomers Appendix A.3.10. Medical devices Table A.102. Polymers and elastomers used in medical devices (including medical device production) Features: Features by being used as sealant: Heat resistance, cold resistance, wear resistance, shock resistance, chemical resistance, etc. Prevents the outflow of oil and other objects to be sealed. Longer life of parts Usage: >100 t/y Usefulness and Benefits of FKM/FFKM The use of FKM/FFKM has brought significant benefits to society's value chain. The unique features of FKM/FFKM can not be realized with other materials. Therefore, the technical feasibility is nil. FKM/FFKM's unparalleled chemical and heat resistance and unique electrical performance, combined with its stability, provide durable and durable performance in every application, contributing to extended product life. About Alternative Materials Our research into FKM alternatives has shown that materials other than FKM/FFKM often fail to meet the critical performance characteristics of FKM/FFKM-based materials, and that FKM/FFKM-based materials often fail to meet multiple characteristics and ranges that are essential for the applications in which they are needed. Problems and Disadvantages of Restricting PFAS Broad PFAS regulations (including PFHxA and PFBA regulations) can result in: Unacceptable deterioration in production costs due to the use of alternative materials due to significantly lower performance levels and longevity. Serious deterioration in product safety. Serious impact on social infrastructure and human life. Negative impact on emerging and growing technology markets such as energy storage, electrification, renewable energy and hydrogen. In addition to the need to redesign products, unacceptable constraints on products that need to meet stringent standard requirements (e.g., safety standards) arise. Safety evaluation of PFASs FKM/FFKMs are classified as PFAS1 based solely on their molecular structure. However, their environmental and toxicological assessments clearly differ from the majority of other low-molecular-weight PFASs in the following respects: In general, the properties of many FKM/FFKMs do not exhibit the environmental and toxicological assessments associated with some PFASs of concern. FKM/FFKMs are chemically stable, non-toxic, biologically available, non-water-soluble, non-mobile substances that are judged to have no significant impact on the environment and human health. Contents of the appeal We believe that the proposed PFAS REACH regulations should result in the exemption of FKM/FFKM from any regulatory action under the REACH regulations, recognizing its importance in the safe use and application of FKM/FFKM by distinguishing diverse PFAS groups according to their respective risk assessments and characteristics. |

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| 3960 | Date:  2023/04/28 05:05  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties. Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm. 6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.1. uses: ANNEX XV Conditions of restriction 5 a) ANNEX A.2.1.5.1. Polymerisation aid 　 CAS RN: products 13252-14-7 13252-13-6 raw materials 13252-14-7 |
| Answer to specific info request 8:  uses: ANNEX XV Conditions of restriction 5 a) ANNEX A.2.1.5.1.Polymerisation aid 　 Function: Lower costs by improving stability and productivity when manufacturing polymer PFAS Usefulness and Benefits of Polymerisation aid The use of Polymerisation aid can provide significant productivity benefits. The productivity benefits of Polymerisation aid can not be realized with other substances other than those that fall under PFAS-related substances like these Polymerisation aid. Therefore, the technical feasibility is nil. The production of many products would be impossible without the use of Polymerisation aid or these Polymerisation aid as well as other PFAS-related substances. About alternative materials As a result of investigating alternative materials for Polymerisation aid, we found that materials other than those that fall under PFAS-related substances, like these Polymerisation aid, often fail to meet important performance characteristics for some polymeric PFASs(such as FFKM) and fail to meet multiple characteristics and ranges that are essential for applications. Problems and Disadvantages of Restricting PFAS Widespread PFAS regulations (including PFHxA and PFBA regulations) can result in: Unacceptable deterioration in production costs due to the use of alternative materials because only products with significantly lower performance levels and life spans can be manufactured. Serious deterioration in product safety. Serious impact on social infrastructure and human life. Negative impact on emerging and growing technology markets such as energy storage, electrification, renewable energy and hydrogen. In addition to the need to redesign products, unacceptable constraints arise on products that must meet stringent standard requirements (e.g., safety standards). Safety evaluation of PFASs Polymerisation aid is classified as PFAS1 based solely on its molecular structure. The properties of Polymerisation aid do not indicate the environmental assessment associated with some PFAS of concern. Content of the appeal We believe that the proposed PFAS REACH regulations should distinguish diverse PFAS groups according to their respective risk assessments and characteristics, recognize the importance of Polymerisation aid in safe use and application, and result in the exemption of Polymerisation aid from any regulatory action under the REACH regulations. |