**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.

|  |  |  |
| --- | --- | --- |
| 3961 | Date:  2023/04/28 05:19  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\_A.3.12.1. Uses\_Table A.47. Uses of PFASs in the production process of electronics and semiconductor products and components. Complemented by a stakeholder.\_Sealing CAS RN: products 25684-76-8 163336-49-0 26425-79-6 raw materials 13252-14-7 |
| Answer to specific info request 7:  uses: ANNEX XV Conditions of restriction 5 ee) ANNEX A.3.12.Electronics and semiconductors\_A.3.12.1. Uses\_Table A.47. Uses of PFASs in the production process of electronics and semiconductor products and components. Complemented by a stakeholder.\_Sealing Features: Describe features by being used as a semiconductor material: heat resistance, cold resistance, wear resistance, impact resistance, chemical resistance, electrical properties, insulation, permeability, weather resistance, ozone resistance, etc. Longer component life by improved heat resistance Improved maintainability Non-fungible levels of chemical and plasma resistance Usage: 10-100 tons/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 has unparalleled chemical and heat resistance, and unique electrical performance, plus stability, which provides durable and durable performance in every application and contributes to extended product life. About Alternative Materials Our research into FKM/FFKM 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 fail to meet the multiple characteristics and ranges that are time unlimited for the applications in which they are needed. Problems and Disadvantages of Restricting PFAS Extensive PFAS regulations (including PFHxA and PFBA regulations) can result in: An 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/FFKM is classified as PFAS1 based solely on its molecular structure. However, its environmental and toxicological assessment clearly differs from most other low-molecular-weight PFASs in the following respects: In general, many FKM/FFKM properties do not exhibit environmental and toxicological assessments associated with some PFASs of concern. FKM/FFKM is a chemically stable, non-toxic, biologically available, non-water-soluble, non-mobile substance determined to have no significant impact on the environment and human health. Content 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 the importance in the safe use and application of FKM/FFKM by distinguishing diverse PFAS groups according to their respective risk assessments and characteristics. |

|  |  |  |
| --- | --- | --- |
| 3962 | Date:  2023/04/28 05:34  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 | 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.2.15. uses: ANNEX XV Conditions of restriction 6 f) ANNEX A.3.2.1.2.Fluoroelastomers\_Table A.13.\_Industrial A.3.2.1.2.Fluoroelastomers A.3.16.1.3.Uses of fluoropolymers in the petroleum industry A.3.2.1.1.Fluoropolymers A.3.2.1.2.Fluoroelastomers\_Table A.13.\_Aerospace A.3.16.1.4.Use of fluoropolymers in mining 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 8:  uses: ANNEX XVConditions of restriction 6 f) ANNEX A.3.2.1.2.Fluoroelastomers\_Table A.13.\_Industrial A.3.2.1.2.Fluoroelastomers A.3.16.1.3.Uses of fluoropolymers in the petroleum industry A.3.2.1.1.Fluoropolymers A.3.2.1.2.Fluoroelastomers\_Table A.13.\_Aerospace A.3.16.1.4.Use of fluoropolymers in mining Features: Features by being used as sealant: Heat resistance, cold resistance, wear resistance, impact resistance, chemical resistance, electrical properties, insulation, permeability, weather resistance, ozone resistance, etc. Prevention of oil and other spills to be sealed. Longer life of parts Usage: >100 tons/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/FFKM 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-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 from any regulatory action under the REACH regulations, after distinguishing diverse PFAS groups according to their respective risk assessments and characteristics and recognizing its importance in the safe use and application of FKM/FFKM. |

|  |  |  |
| --- | --- | --- |
| 3963 | Date:  2023/04/28 06:51  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 No derogation ANNEX A.3.12. Electronics and semiconductors\_Table A.48. Uses and properties of PFASs in the electronics industry identified by stakeholders.\_Coating of electronic components CAS RN: raw materials 9011-17-0 |
| Answer to specific info request 8:  uses: ANNEX XV No derogation ANNEX A.3.12. Electronics and semiconductors\_Table A.48. Uses and properties of PFASs in the electronics industry identified by stakeholders.\_Coating of electronic components Functions: Heat resistance, moisture resistance, chemical resistance Usage: < 1 t/y [Usefulness, Benefits] Fluorinated adhesives have unparalleled heat, moisture, chemical, and electrical insulation properties, as well as stability, which provides durable and durable performance in every application and contributes to extending the life of products such as automobiles, which are used in harsh environments. About alternative materials Heat-resistant adhesives such as silicone and epoxy adhesives are available on the market, but they do not have the same heat resistance, moisture resistance, chemical resistance and electrical insulation as fluorine adhesives. These performances are required for circuit boards of power semiconductors, which are expected to be used in the future, and the importance of fluorine adhesives is expected to increase in the future. Problems and Disadvantages of Restricting PFAS Broad PFAS regulations (including PFHxA and PFBA regulations) may result in: The use of alternative materials due to their vastly inferior performance levels and lifespans seriously deteriorates product safety and seriously affects social infrastructure and human life. Safety evaluation of PFASs Environmental and toxicological evaluations clearly differ from the majority of other low-molecular-weight PFASs in the following respects: In general, the properties of many fluororesins do not exhibit environmental and toxicological evaluations associated with some PFASs of concern. Conversely, specifically, recent studies have shown that 16 commercially available fluororesins meet the OECD's Polymer of Low Concern criteria. These resins are chemically stable, non-toxic, biologically available, non-water-soluble, and non-mobile substances that are determined to have no significant impact on the environment and human health. Fluorine release agents, and the fluorine telomers they are made from, have tested negative in mutagenicity tests and the proposed restrictions on handling them are not immediately applicable. We believe that the proposed PFAS REACH regulations should result in exempting fluorinated resins from any regulatory action under the REACH regulations, recognizing their importance in the safe use and application of fluorinated resins by distinguishing diverse PFAS groups according to their respective risk assessments and characteristics. In particular, we urge that fluorinated adhesives and their raw materials, fluorinated resins, be exempted from the PFAS regulations as time unlimited uses, recognizing their importance. |

|  |  |  |
| --- | --- | --- |
| 3964 | Date:  2023/04/28 07:03  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: uses: ANNEX XV Conditions of restriction 6 a) ANNEX A.3.2.1.2. Fluoroelastomers\_Table A.13.\_seals in food handling processes 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 Conditions of restriction 6 a) ANNEX A.3.2.1.2. Fluoroelastomers\_Table A.13.\_seals in food handling processes Fluoroelastomers\_Table A.13.\_seals in food handling processes 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/FFKM alternatives has shown that materials other than FKM/FFKM often fail to meet the critical performance characteristics of FKM-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 arise on products that must meet stringent standard requirements (e.g., safety standards). 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. |

|  |  |  |
| --- | --- | --- |
| 3965 | Date:  2023/04/28 07:14  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\_Table A.49. Uses and properties of PFASs in the semiconductor industry identified by stakeholders.\_Semiconductor Products and components\_Adhesive CAS RN: raw materials 9011-17-0 |
| Answer to specific info request 7:  uses: ANNEX XV Conditions of restriction 5 ee) ANNEX A.3.12. Electronics and semiconductors\_Table A.49. Uses and properties of PFASs in the semiconductor industry identified by stakeholders.\_Semiconductor Products and components\_Adhesive Functions: Heat resistance, moisture resistance, chemical resistance Usage: < 1 t/y [Usefulness, Benefits] Fluorinated adhesives have unparalleled heat, moisture, chemical, and electrical insulation properties, as well as stability, which provides durable and durable performance in every application and contributes to extending the life of products such as automobiles, which are used in harsh environments. About alternative materials Heat-resistant adhesives such as silicone and epoxy adhesives are available on the market, but they do not have the same heat resistance, moisture resistance, chemical resistance and electrical insulation as fluorine adhesives. These performances are required for circuit boards of power semiconductors, which are expected to be used in the future, and the importance of fluorine adhesives is expected to increase in the future. [Problems and Disadvantages of Restricting PFAS] Broad PFAS regulations (including PFHxA and PFBA regulations) may result in: The use of alternative materials due to their vastly inferior performance levels and lifespans seriously deteriorates product safety and seriously affects social infrastructure and human life. Safety evaluation of PFASs Environmental and toxicological evaluations clearly differ from the majority of other low-molecular-weight PFASs in the following respects: In general, the properties of many fluororesins do not exhibit environmental and toxicological evaluations associated with some PFASs of concern. Conversely, specifically, recent studies have shown that 16 commercially available fluororesins meet the OECD's Polymer of Low Concern criteria. These resins are chemically stable, non-toxic, biologically available, non-water-soluble, and non-mobile substances that are determined to have no significant impact on the environment and human health. Fluorine release agents, and the fluorine telomers they are made from, have tested negative in mutagenicity tests and the proposed restrictions on handling them are not immediately applicable. We believe that the proposed PFAS REACH regulations should result in exempting fluorinated resins from any regulatory action under the REACH regulations, recognizing their importance in the safe use and application of fluorinated resins by distinguishing diverse PFAS groups according to their respective risk assessments and characteristics. In particular, we urge that fluorinated adhesives and their raw materials, fluorinated resins, be exempted from the PFAS regulations as time unlimited uses, recognizing their importance. |

|  |  |  |
| --- | --- | --- |
| 3966 | Date:  2023/04/28 07:30  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:- uses: ANNEX XV ANNEX A.2.1. PFASs manufacture CAS RN: products 375-50-8 85737-06-0 359-08-0 |
| Answer to specific info request 6:  uses: ANNEX XV ANNEX A.2.1. PFASs manufacture Use: Polymerization auxiliary (fluorine-based auxiliary material) Function: Lower costs by improving stability and productivity during the production of polymer PFAS Usefulness and merits of secondary materials The use of these sub-materials can yield significant productivity benefits. The benefits of improving properties with these sub-materials can not be realized with other substances other than those that fall under PFAS-related substances. Therefore, there is no alternative technical feasibility. The production of many products would be impossible without using substances that fall under PFAS-related substances as well as these sub-materials. About alternative materials As a result of investigating these sub-materials, we found that materials other than those that fall under PFAS-related substances, like these sub-materials, often fail to meet important performance characteristics and fail to meet multiple characteristics and ranges that are essential for their application. [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 on products that need to meet stringent standard requirements (e.g., safety standards) arise. Safety evaluation of PFASs These sub-materials are classified as PFAS1 based solely on their molecular structure. The properties of these sub-materials do not indicate environmental and toxicological assessments associated with some PFAS of concern. Content of the claim 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 these sub-materials in their safe use and application, and result in their exemption from any regulatory action under the REACH regulations. |

|  |  |  |
| --- | --- | --- |
| 3967 | Date:  2023/04/28 08:02  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 used in hollow fiber filtration membrane modules used in the pharmaceutical manufacturing process from this restriction. The membrane filtration method is suitable for long-term continuous culture of high-density cells and produces higher termite production per day than batch culture. In addition, since continuous culture is a continuous process, it is expected to reduce contamination risk and improve quality safety. It is hoped that safer drugs will be available at lower prices. - Manufacturing equipment must be physically and chemically durable. We have confirmed that our fluoropolymer components can withstand each sterilization process required in the pharmaceutical manufacturing process. Strong durability and the ability to be cleaned with chemicals ensure stable operation. - 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:  Pharmaceutical manufacturing instrument |
| 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 5:  Not designated as proposed derogations |
| Answer to specific info request 6:  b) - The membrane filtration method is suitable for long-term continuous culture of high-density cells and produces higher termite production per day than batch culture. In addition, since continuous culture is a continuous process, it is expected to reduce contamination risk and improve quality safety. It is hoped that safer drugs will be available at lower prices. - Module parts must be physically and chemically durable. We have confirmed that our fluoropolymer components can withstand each sterilization process required in the pharmaceutical manufacturing process. The strong durability and ability to be cleaned with chemicals enable stable operation. - 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) - Batch process (centrifugation) produces low antibody yield. There is a risk of contamination because the liquid is changed each time. - Disposable flat membranes cannot be installed in actual manufacturing facilities because of the low volume they can process. - The use of hollow fiber membranes allows for the continuous production of pharmaceuticals and low risk of contamination, making the production of pharmaceuticals inexpensive and safe. Among hollow fiber membranes, there is no alternative to Fluoropolymer in terms of durability and stability. (See confidential attachment) f) i, ii There is no technically and economically feasible alternative. f) iii - Methods other than hollow fiber membrane filtration significantly reduce production efficiency and contamination risk, leading to higher production costs, short supply, and lower quality of pharmaceutical products. - With commodity polymers, there is a risk that the sterilization process will degrade the raw material and the degraded substances will enter the pharmaceutical product. They are less durable to chemicals than fluoropolymer, and there is a risk that the hollow fiber membranes cannot be adequately cleaned. Fluoropolymer offers long-term, stable operation and is superior in terms of pharmaceutical cost and safety. g) - There is a risk that changes in the way pharmaceuticals are manufactured will increase manufacturing costs and make it impossible to produce pharmaceuticals of the same quality. - Many stakeholders, from drug manufacturers to patients, will be affected. Rising prices and declining production of pharmaceuticals lead to social problems, as more patients die due to lack of access to medicines. - The April 5 ECHA webinar materials do not list PFAS emissions from pharmaceutical manufacturing equipment, and we recognize that emissions are very low. Therefore, the impact of PFAS in pharmaceutical manufacturing equipment on human health and the environment is very small. It is clear which risk is greater, the risk of dying from PFAS or the risk of dying from lack of pharmaceuticals by PFAS restriction. |
| Answer to specific info request 7:  - In the case of facilities that manufacture products that are directly ingested by the human body, such as pharmaceuticals, there must be no foreign matter or eluted substances. Fluoropolymer is a stable polymer and its degradation products do not leach into pharmaceuticals. In addition, they do not disassemble during the sterilization process or chemical cleaning, so they can be kept safe. - Our membrane modules were approved as a GMP production of pharmaceuticals. |
| 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. |

|  |  |  |
| --- | --- | --- |
| 3968 | Date:  2023/04/28 09:00  Content:  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan | General Comments:  Fluoroelastomer(fluorine rubber), fluoroplastic(fluorine resin), fluorinated grease/oil should be exempted from the regulations because there is no evidence of harm. Most fluoroelastomer(fluorine rubber) also contains bisphenol AF, a type of PFAS. The draft regulations for bisphenol AF are published in "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment". It can be said that the proposed regulations set an upper limit for the release into the environment and the environmental impact has been sufficiently examined. The threshold for bisphenol AF in moldings should follow the values in this proposed regulation.  Six months is not enough public consultation. Fluoroelastomer(fluorine rubber), fluoroplastic(fluorine resin), fluorinated grease/oil are used in various parts of industrial products and perform as essential parts. Public consultation covering all of these takes more than 12 months.  A transition period of 18 months is too short. Fluoroelastomer(fluorine rubber), fluoroplastic(fluorine resin), fluorinated grease/oil are used in various parts of industrial products and perform as essential parts. A short transition period not only disrupts the market, but can also cause accidents that affect the environment and human life because the necessary products are not available. A transition period of 36 months or more is probably necessary.  This regulation conflicts with the CE Principles and the Green Deal goals because it prevents the repair and inspection of vehicles already on the market. Fluoroelastomer(fluorine rubber), fluoroplastic(fluorine resin), fluorinated grease/oil contribute to the safety of vehicles and contribute to the decarbonization and decontamination of industries. Therefore, Fluoroelastomer(fluorine rubber), fluoroplastic(fluorine resin), fluorinated grease/oil and greases should be exempted with Time-unlimited.  Instead of targeting more than 10,000 PFAS from the start, as in the German-proposed "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment" for which public consultations are currently being conducted, a realistic approach would be to create a list of substances or groups of substances with unacceptable risks, and then set conditions for adding them to the list. PFAS can be divided into several “subgroups”, so for example, “PFCA” such as PFOA and “PFSA” such as PFOS are PFAS with unacceptable risks to human health and the environment. Because of the evidence, we include these two subgroups in the first list and add them to the list with the condition that they are not only "extremely persistent", but also comply with the CLP regulations for human health and environmental hazards. should add categories in the harmonized classification (eg reproductive toxicity, endocrine disrupting, etc.). |

|  |  |  |
| --- | --- | --- |
| 3969 | Date:  2023/04/28 09:20  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data Product drawing | Answer to specific info request 1:  Transport |
| Answer to specific info request 7:  Oil seals used in engines of transportation equipment a. Type of PFAS FKMs, bisphenol AF b. Major functions of PFAS It prevents leakage of lubricating oil while maintaining the lubricating performance of the bearings as a rotary shaft seal for vehicular engines. It provides functionality and safety until the product life of the vehicle (approximately 20 years) without deterioration by heat or lubricating oil in an environment reaching 200 deg.C. g. Substitution is not technically or economically feasible The ambient temperature of the engine part is usually around 150 deg.C, but oil seals have sliding heat generation, so heat resistance of around 150 ~ 200 deg.C is required. Also, contact with engine oil requires the oil resistance class of ASTM D 2000 to be at least "E." The heat resistance evaluation results for materials of oil resistance class "E" or higher are, for example, 1/100 to 1/500 for NBR, 1/40 to 1/80 for ACM and HNBR, and 1/10 to 1/20 for VMQ in comparison with FKM at 175 degrees C. This value is proportional to the life, and even the most heat-resistant VMQ has a life of 1/10 to 1/20, which means that parts must be replaced about once every 1 to 2 years. Thus, the number of 0 replacements increases to more than 10 over the life of the product, and the amount of waste with environmental impact increases more than 10 times. Replacing seal parts requires removing the engine from the engine bay, which is a significant financial burden. Failure to do so will result in increased environmental pollution from oil leaks and, in the worst case, an accident resulting from engine failure and the fatal impact of engine fire. Thus, FKM (perfluoro and polyfluoropolymers) is an important material to reduce environmental impact and protect human lives. Therefore, FKM (perfluoro and polyfluoropolymers) is not subject to regulation and its continued use in Time-unlimited is essential. The above is exactly the same for engines of construction, industrial and agricultural machinery. It can be said that the prohibition of putting vehicles on the market after type approval for a certain period of time violates the concept of the ELV Directive because it prevents recovery of development costs of vehicles. The prohibition of putting supply parts on the market for a certain period of time violates CE principles and Green Deal goals because it prevents repair and inspection of vehicles already on the market. Type certification systems and supplies should be recognized as important requirements for exemptions. In addition, the use of FKM (perfluoro and polyfluoropolymers) to form molded products with rubber elasticity requires the use of bisphenol AF, a type of PFAS, as a cross-linker. Proposed regulations for bisphenol AF have been published in the "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment". It can be said that the proposed regulations have established upper limits for the release of bisphenol AF into the environment and that the environmental impact has been sufficiently examined. The threshold for bisphenol AF in molded products should be in accordance with the values in this proposed legislation. The use of FKM (perfluoro and polyfluoropolymers) is exempted from PFAS regulations, and its continued use with Time-unlimited is essential. The above is exactly the same for engines of construction, industrial and agricultural machinery. |

|  |  |  |
| --- | --- | --- |
| 3970 | Date:  2023/04/28 09:27  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data Product drawing | Answer to specific info request 1:  Other niche applications |
| Answer to specific info request 6:  Oil seals used in engines of construction, industrial and agricultural machinery a. Type of PFAS FKMs, bisphenol AF b. Key functions of PFAS It prevents leakage of lubricating oil while maintaining the lubricating performance of bearings as a rotary shaft seal in engines for construction, industrial and agricultural machinery. It provides functionality and safety until the product life of the vehicle (approximately 20 years) without deterioration by heat or lubricating oil in an environment reaching 200 deg.C. g. Substitution is not technically or economically feasible The ambient temperature of the engine part is usually around 150 deg.C, but oil seals have sliding heat generation, so heat resistance of around 150 ~ 200 deg.C is required. Also, contact with engine oil requires the oil resistance class of ASTM D 2000 to be at least "E." The heat resistance evaluation results for materials of oil resistance class "E" or higher are, for example, 1/100 to 1/500 for NBR, 1/40 to 1/80 for ACM and HNBR, and 1/10 to 1/20 for VMQ in comparison with FKM at 175 degrees C. This value is proportional to the life, and even the most heat-resistant VMQ has a life of 1/10 to 1/20, which means that parts must be replaced about once every 1 to 2 years. Thus, the number of 0 replacements increases to more than 10 over the life of the product, and the amount of waste with environmental impact increases more than 10 times. Replacing seal parts requires removing the engine from the engine bay, which is a significant financial burden. Failure to do so will result in increased environmental pollution from oil leaks and, in the worst case, an accident resulting from engine failure and the fatal impact of engine fire. Thus, FKM (perfluoro and polyfluoropolymers) is an important material to reduce environmental impact and protect human lives. Therefore, FKM (perfluoro and polyfluoropolymers) is not subject to regulation and its continued use in Time-unlimited is essential. Banning supply parts from being put on the market for a certain period of time violates the CE principles and the Green Deal goals because it prevents the repair and inspection of vehicles already on the market. Supplies should be recognized as an important requirement for exemption. In addition, the use of FKM (perfluoro and polyfluoropolymers) to form molded products with rubber elasticity requires the use of bisphenol AF, a type of PFAS, as a cross-linking agent. Proposed regulations for bisphenol AF have been published in the "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment". It can be said that the proposed regulations have established upper limits for the release of bisphenol AF into the environment and that the environmental impact has been sufficiently examined. The threshold for bisphenol AF in molded products should be in accordance with the values in this proposed legislation. The use of FKM (perfluoro and polyfluoropolymers) is exempted from PFAS regulations, and its continued use with Time-unlimited is essential. |

|  |  |  |
| --- | --- | --- |
| 3971 | Date:  2023/04/28 09:34  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | Answer to specific info request 1:  Transport |
| Answer to specific info request 7:  Fuel O-rings, oil seals used around engines in transportation equipment a. Type of PFAS FKMs, bisphenol AF b. Key functions of PFAS Fuel leakage is prevented as an O-ring or oil seal in the fuel supply system of engines used in vehicles. It provides functionality and safety until the product life of the vehicle (approximately 20 years) without deterioration by heat or fuel in an environment that reaches 150 deg.C. g. Substitution is not technically or economically feasible Vehicle engines have fueling systems with fixed seal O-rings for injection nozzles and dynamic seal oil seals for fuel supply pumps. Because these seals are used in and near the engine, the environmental temperature can reach over 150 deg.C. The suitability of the materials used for these seals is determined by liquid resistance. The Liquid resistance of the materials shows that ACM, HNBR and high heat resistant NBR can not be used in tests with the equivalent of fuel oil, Fuel C, due to their large swelling. The less swelling materials are FKM and low heat resistant NBR, but only FKM (perfluoro and polyfluoropolymers) can be applied to these sealing materials due to environmental temperature constraints. Since only FKM (perfluoro and polyfluoropolymers) can be used as these sealing products, their continued use in Time-unlimited is essential. The use of materials other than FKM will lead to increased environmental pollution due to fuel leaks and, in the worst case, to accidents due to engine failure and the impact of engine fires on human lives. Thus, FKM (perfluoro and polyfluoropolymers) is an important material to reduce environmental impact and protect human lives. Therefore, FKM (perfluoro and polyfluoropolymers) is not subject to regulation and its continued use in Time-unlimited is essential. The above is exactly the same for fuel supply system O-rings and oil seals for construction, industrial and agricultural machinery. It is against the idea of the ELV Directive to prohibit the sale of vehicles after type approval for a certain period of time because it prevents recovery of development costs for vehicles. Banning the sale of supply parts for a certain period of time violates CE principles and Green Deal goals because it prevents the repair and inspection of vehicles already on the market. Type certification systems and supplies should be recognized as important requirements for exemptions. In addition, the use of FKM (perfluoro and polyfluoropolymers) to form molded products with rubber elasticity requires the use of bisphenol AF, a type of PFAS, as a cross-linker. Proposed regulations for bisphenol AF have been published in the "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment". It can be said that the proposed regulations have established upper limits for the release of bisphenol AF into the environment and that the environmental impact has been sufficiently examined. The threshold for bisphenol AF in molded products should be in accordance with the values in this proposed legislation. The use of FKM (perfluoro and polyfluoropolymers) is exempted from PFAS regulations, and its continued use with Time-unlimited is essential. The above is exactly the same for the fuel supply system O-rings and oil seals for construction, industrial and agricultural machinery. |

|  |  |  |
| --- | --- | --- |
| 3972 | Date:  2023/04/28 09:43  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | Answer to specific info request 1:  Transport |
| Answer to specific info request 7:  Oil seals used in gearbox and AT of transportation equipment a. Types of PFAS FKMs, Bisphenol AF b. Key functions of PFAS Prevents leakage of lubricating oil while maintaining the lubricating performance of bearings as the rotary shaft seal of gearbox and AT(automatic transmission) used in vehicles. It provides functionality and safety until the product life of the vehicle (approximately 20 years) without deterioration by heat or lubricating oil in an environment reaching 150 deg.C. g. Substitution is not technically or economically feasible Transmission systems such as gearbox and AT are used for the drivetrain of vehicles because of the advantages of engine performance and economy. Since these transmissions have bearings and use lubricating oil, an oil seal is essential to seal the lubricating oil. Since the temperature around the transmission reaches 150 deg.C, the oil seal must have both oil and heat resistance. NBR, ACM and VMQ other than FKM can ensure function and safety until the product life (20 years) when the normal temperature is around 100 deg.C. However, with the advanced performance of modern transportation equipment, the temperature of these products reaches 150 deg.C. As the attached data shows, the product life is shortened by 1/10 at 150 deg.C compared to 100 deg.C. That is, the parts need to be replaced once every 2 years. Thus, the number of 0 replacements increases to more than 10 over the life of the product, and the amount of waste with environmental impact increases by more than 10 times. Replacing seal parts requires removing the gearbox or AT from the engine bay, which is economically costly. Failure to do so can lead to increased environmental pollution from oil leaks and, in the worst case, an accident or a vehicle fire resulting from damage to the gearbox or AT, which can have a fatal impact on human life. Thus, FKM (perfluoro and polyfluoropolymers) is an important material that reduces environmental impact and protects human life. Therefore, FKM (perfluoro and polyfluoropolymers) is not subject to regulation, and its continued use with Time-unlimited is essential. The above is exactly the same for gearbox and AT of construction, industrial and agricultural machines. Prohibiting a vehicle from being put on the market after type certification for a certain period of time would be contrary to the concept of the ELV Directive because it would prevent the recovery of development costs for the vehicle. Prohibiting supply parts from being put on the market for a certain period of time would interfere with the CE principles and the Green Deal goals because it would prevent the repair and inspection of vehicles already on the market. Type certification systems and supplies should be recognized as important requirements for exemptions. In addition, the use of FKM (perfluoro and polyfluoropolymers) to form molded products with rubber elasticity requires the use of bisphenol AF, a type of PFAS, as a cross-linker. Proposed regulations for bisphenol AF have been published in the "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment". It can be said that the proposed regulations have established upper limits for the release of bisphenol AF into the environment and that the environmental impact has been sufficiently examined. The threshold for bisphenol AF in molded products should be in accordance with the values in this proposed legislation. The use of FKM (perfluoro and polyfluoropolymers) is exempted from PFAS regulations, and its continued use with Time-unlimited is essential. The above is exactly the same for engines of construction, industrial and agricultural machinery. |

|  |  |  |
| --- | --- | --- |
| 3973 | Date:  2023/04/28 09:50  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | Answer to specific info request 1:  Transport |
| Answer to specific info request 7:  Oil seals used in motors of transportation equipment a. Types of PFAS FKMs, Bisphenol AF b. Key functions of PFAS It prevents leakage of lubricating oil while maintaining the lubricating performance of the bearings as a rotary shaft seal for motors used in vehicles. It provides functionality and safety until the product life of the vehicle (approximately 20 years) without deterioration by heat or lubricating oil in an environment reaching 200 degrees Celsius. g. Substitution is not technically or economically feasible The use of vehicle engines has been discontinued, and the adoption of motors driven by batteries and the like has been increasing. In the future, the ratio of motorized vehicles to engine-powered vehicles is expected to increase. Oil seals used for the bearings of these motor drive shafts require both heat resistance in an environment where sliding heat generation reaches 200 degrees Celsius under high-speed rotation and oil resistance that is not destroyed by lubricating oil. By coming into contact with lubricating oil, the oil resistance class of the ASTM D 2000 requires an "E" or higher. The heat resistance evaluation results for materials with an oil resistance class of "E" or higher are, for example, 1/100 to 1/500 for NBR, 1/40 to 1/80 for ACM and HNBR, and 1/10 to 1/20 for VMQ in comparison with FKM at 175 degrees C. This value is proportional to the life, and even the most heat-resistant VMQ has a life of 1/10 to 1/20, which means that parts must be replaced about once every 1 to 2 years. Thus, the number of 0 replacements increases to more than 10 over the life of the product, and the amount of waste with environmental impact increases more than 10 times. Replacing seal parts requires removing the engine from the engine bay, which is a significant financial burden. Failure to do so will result in increased environmental pollution from oil leaks and, in the worst case, an accident resulting from engine failure and the fatal impact of engine fire. Thus, FKM (perfluoro and polyfluoropolymers) is an important material to reduce environmental impact and protect human lives. Therefore, FKM (perfluoro and polyfluoropolymers) is not subject to regulation and its continued use in Time-unlimited is essential. The above is exactly the same for motors of construction, industrial and agricultural machines. Prohibiting vehicles from being put on the market after type certification for a certain period of time is against the idea of the ELV Directive because it prevents recovery of development costs for vehicles. Prohibiting supply parts from being put on the market for a certain period of time violates the CE Principles and the Green Deal goals because it prevents repair and inspection of vehicles already on the market. Type certification systems and supplies should be recognized as important requirements for exemptions. In addition, the use of FKM (perfluoro and polyfluoropolymers) to form molded products with rubber elasticity requires the use of bisphenol AF, a type of PFAS, as a cross-linker. Proposed regulations for bisphenol AF have been published in the "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment". It can be said that the proposed regulations have established upper limits for the release of bisphenol AF into the environment and that the environmental impact has been sufficiently examined. The threshold for bisphenol AF in molded products should be in accordance with the values in this proposed legislation. The use of FKM (perfluoro and polyfluoropolymers) is exempted from PFAS regulations, and its continued use with Time-unlimited is essential. The above is exactly the same for motors of construction, industrial and agricultural machines. |

|  |  |  |
| --- | --- | --- |
| 3974 | Date:  2023/04/28 14:48  Content:  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Eugster / Frismag AG  Org. country:  Switzerland  Attachment:  <redacted>  Privacy statement:  Protection of commercial interests of our company | General Comments:  There are various applications of PFAS in food contact materials in consumer cookware, amongst others seals, O-rings, gaskets, tubing and pipes in consumer electrical equipment such as coffee machines (mentioned under the sixth bullet point on page 39 of Annex A where consumer cookware is divided in 7 different sub-uses). However, the Impact Assessment for consumer cookware in Annex E focuses exclusively on non-stick coatings (chapter E.2.3.2.2 on alternatives, chapter E.2.3.2.6 on substitution potential, chapter E.2.3.4.2 on impacts on consumers, impacts on society, cost-effectiveness, and practicability and monitorability). This is also reflected in the summary table on the assessment of costs and benefits for consumer cookware and home kitchen appliances (Table E.52 on p. 177 of Annex E) which states in the column “Alternatives” that “There is sufficiently strong evidence that technically and economically feasible alternative non-stick coatings are available for the domestic market, and already have significant market share” and in the row “Conclusion” that “A full ban after a derogation period of 18 months is concluded as feasible for the consumer non-stick coatings market”, not taking into account at all the sub-uses in consumer electrical equipment mentioned above. In fact, the requirements for tubing and seals with food contact in electrical household appliances like coffee machines regarding temperature stability, pressure stability, chemical resistance (to cleaning and descaling agents) and food compliances are the same as in professional appliances and very similar to the ones for equipment for the industrial food and feed production. Accordingly, there are currently no alternatives available for the majority of the uses in this sub-sector, just as it has been concluded for industrial food and feed production equipment in Annex E. In addition, even if alternative materials are found that fulfill the aforementioned requirements, it is very unlikely that 1:1 alternatives exist. As a consequence, if the affected components made from potential alternative materials are heavier, larger (e.g. because thicker tubes are necessary to achieve the same pressure stability) or slightly less resistant to pressure or temperature, the entire design of an appliance must be adapted. This will not be possible within the proposed transition period of 18 months, even if suitable alternative materials are found. Therefore, we request that proposed derogation 6.a in RO2 for fluoropolymers and perfluoropolyethers for the use in food contact materials for the purpose of industrial and professional food and feed production is extended to electrical household appliances. The environmental impacts of such an extended derogation have already been assessed in chapter E.2.3.3 of Annex E during the assessment of the environmental impacts of the proposed derogation for food contact materials for the purpose of industrial and professional food and feed production: As no data was available for quantifying the amount of additional emissions for this specific derogation, the environmental impacts were evaluated qualitatively in relation to a worst-case additional emission scenario, assuming a full derogation of fluoropolymers for the whole food contact materials and packaging sector. In relation to this reference scenario, which includes the use of fluoropolymers in electrical household appliances, additional emissions of the proposed derogation have been considered to be small. We therefore consider a derogation for fluoropolymers and perfluoropolyethers for the use in food contact materials in electrical household appliances justifiable. |
| Answer to specific info request 1:  Food contact materials and packaging -> Consumer cookware |
| Answer to specific info request 5:  Proposed derogation 6.a for fluoropolymers and perfluoropolyethers currently only applies to food contact materials for the purpose of industrial and professional food and feed production. As we requested in our general comment that this derogation is extended to electrical household appliances, information is provided on the tonnage of PFAS used by our company for this application. The information is added as a confidential attachment in section V. |

|  |  |  |
| --- | --- | --- |
| 3975 | Date:  2023/04/28 15:41  Type:  BehalfOfAnOrganisation  Org. type:  Academic institution  Org. name:  OST - Ostschweizer Fachhochschule Inst. for Energy Systems  Org. country:  Switzerland  Attachment: | Answer to specific info request 6:  see attached document |
| Answer to specific info request 7:  see attached document |

|  |  |  |
| --- | --- | --- |
| 3976 | Date:  2023/04/28 15:45  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Doerken Coatings GmbH & Co. KG  Org. country:  Germany | General Comments:  Dörken Coatings GmbH & Co. KG is a manufacturer of decorative and industrial coatings. As a general rule, these consist of 5 to 30 components, which in turn are not pure substances but mixtures. In this respect, a formulation consists of approx. 80 single substances, many of which are not subject to classification and labelling requirements. As a result, many of our raw materials may contain PFAS without us being aware of it. In the event of a ban on PFAS, an unexpected number of raw materials will therefore no longer be manufactured and thus no longer be usable. Replacing these in an estimable time frame represents a considerable effort in terms of personnel in R&D, application technology and production. |
| Answer to specific info request 1:  Use in coating materials as a surface additive to adjust particularly smooth surfaces or surfaces with specific properties (coefficients of friction) for industrial application. An example of this is the use in safety belt systems. These must be easy to open and close under normal conditions of use. However, under extreme loads, such as in an accident, they must not open automatically. After the accident, however, it must be possible to unbuckle the belt easily. This application is therefore relevant to safety. |
| Answer to specific info request 2:  PFASs are added to a coating material during an industrial process. The usual amount for decorative coatings is approx. 0.1% and one calculates with 3% total loss during the production process of 0.003%. In this case, the amount of waste is sent for proper disposal. For technical functional surface coatings, the input quantity is between 0.1% and 10%. Thus, an estimated loss rate of 3% results in a released PFAS quantity of 0.003% to 0.3%. This is also fed into proper disposal channels. The PFASs are firmly embedded in the coating, so there is no release if used properly. Unfortunately, we do not have any data on loss rates due to weathering or abrasion. At the end of the life cycle, the component is usually disposed of or recycled properly. Surfaces that have already been coated can also be recoated. |
| Answer to specific info request 5:  Coatings could fall under lubricants after Paragraphs 5s if sliding coatings are also the focus of this exemption. |
| Answer to specific info request 6:  Used in nearly all car seatbelt buckle systems. Currently no functioning alternative known - R&D in progress (estimated development time 2-4 years). Time for certification of the coated components approx. 2.5 years (among other things, numerous crash tests necessary) The costs to be expected for this are obviously in the high 6-digit range. It can be assumed that these costs cannot be passed on to the coating material. An example of this is the use in safety belt systems. These must be easy to open and close under normal conditions of use. However, under extreme stress, such as in an accident, they must not open automatically. After the accident, however, it must be possible to unbuckle the belt easily. This application is therefore safety-relevant. Another example of a safety-relevant component is the chassis screws. These must have a defined friction coefficient (e.g. VDA friction coefficient window). To achieve this, the screws must be smooth enough on one side to be easily screwed in. On the other hand, they must not be too smooth so that they loosen on their own, for example while driving, and thus the chassis falls apart while driving, or the head of the screw is torn off during the screwing process. Furthermore, the surface must not be too rough, otherwise the screw will jam in the worst case and cannot be completely screwed into the chassis. PFAS are ideal and currently without alternative as a component of the lubricant in the screw coating to reliably guarantee this adjustment of the coefficient of friction. These applications affect practically all automobile manufacturers. As no alternatives are yet known, the loss of supplies of seat belt systems is threatening the entire automotive industry. |
| Answer to specific info request 8:  Architectural coatings and paints It is possible that a significant number of our pre-products contain PFAS as auxiliary substances. Should these be regulated, there is a risk of loss of raw material and, in the best case scenario, temporary loss of production. For example, the industry assumes that PFASs are used during the pigment manufacturing process. To ensure the same quality of products, significant reformulations become necessary As mentioned in point 6, the use of PFASs in safety-related applications is essential in the automotive industry. Failure to do so would compromise the safety of vehicles, operators, passengers or goods, except as addressed in other parts of this restriction: Screening and identification of alternative raw materials has been a very high priority for our R&D department for two years now. Waxes, additives and their combination are already showing first success in increasing the friction coefficient, surface homogeneity, workability of the finished product (settling, scrambling, clumping, scratching). However, the development process takes time. At the same time, previously unknown amounts of PFASs in raw materials are disclosed by suppliers, which in turn means additional work for R&D because the formulations have to be adjusted. The PFASs are processed as efficiently as possible at Dörken. There is no contamination of the environment. |

|  |  |  |
| --- | --- | --- |
| 3977 | Date:  2023/04/28 15:50  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Watson-Marlow Fluid Technology Solutions  Org. country:  United Kingdom  Attachment:  <redacted>  Privacy statement:  The information submitted in the confidential attachment includes business data and the sharing of this information would undermine the protection of WMFTS’ commercial interests and intellectual property. | General Comments:  Scope or restriction analysis Watson-Marlow Fluid Technology Solutions (WMFTS), part of Spirax-Sarco Engineering plc (a FTSE 100 list group) comprises ten distinct brands (listed below) providing positive displacement pumps and associated fluid path technologies. Brands and Areas of expertise Watson-Marlow Pumps: Peristaltic tube pumps Watson-Marlow Tubing: Precision tubing Aflex Hose: PTFE lined flexible hose Alitea OEM Pumps: Peristaltic solutions for OEM customers Bredel Hose Pumps: Heavy-duty hose pumps Flexicon Liquid Filling: Aseptic filling and capping systems Masosine Process Pumps: Sinusoidal pumps Biopure: Single-use fluid path components ASEPCO: Weirless Radial diaphragm valves Flowsmart: Sanitary fluid path products  Watson-Marlow Fluid Technology Solutions has 10 world class factories and direct sales operations in 42 countries around the globe, including 7 factories in Germany, Denmark, Sweden, the Netherlands and the UK, and 24 direct sales operations across Europe and the UK. Our products handle the toughest applications in a broad range of industries including: • Biotechnology and pharmaceutical • Food and beverage • Mining • Water and wastewater • Chemical • Automotive and Aerospace • Paint and pigments • Print and packaging • Pulp and paper • General industry WMFTS uses fluoropolymers in the manufacture of many of its products. The volume of products can be found in the confidential attachment report.  Hazard or exposure WMFTS fully supports the restriction of specific, hazardous PFAS that pose a danger due to bioavailability, bioaccumulative and toxic properties e.g. PFOA, PFOS, GenX and C9-14 PFCAs. However, to implement a restriction on a broad group such as PFAS means applying these restrictions to substances that exhibit significantly different properties and characteristics. Fluoropolymers are structurally different to PFAS of concern and have very different properties. Further differentiation can also be made to separate commonly used fluoropolymers such as PTFE, PVDF, FKM from side-chain fluorinated polymers. Fluoropolymers do not exhibit bioavailability, bioaccumulative or toxic characteristics and should therefore be separated from hazardous PFAS and exempt from legislative restrictions. PTFE for example, does not oxidise, hydrolyse, photolyze, degrade by microorganism attack, is not mobile in water and is non-volatile. Fluoropolymers processed by suspension polymerisation (granular PTFE and PVDF) do not require PFAS-based processing aids.  Environmental emissions Fluoropolymer waste is known to be chemically inert, and any fluorinated compounds that may leach from fluoropolymer waste would be contained within landfill leachate collection systems. Furthermore, the most stable fluoropolymer, PTFE, can be effectively incinerated at over 800°C reaching complete thermal decomposition, demonstrating effective disposal methods are available to prevent accumulation of waste fluoropolymer products in landfill. More information can be found in sections 2 and 3 of the confidential attachment report.  Baseline Please see the confidential attachment report.  Description of analytical methods No comment  Information on alternatives Information on alternative materials has been provided for each sector and sub-use. Please see sections 6, 7 and 8 of the confidential attachment report.  Information on benefits No comment  Other socio-economic analysis (SEA) issues Please see information provided for specific applications and industries in sections 6, 7 and 8 of the confidential attachment report.  Transitional period WMFTS uses various fluoropolymers across a wide range of products (more than 150 different products) for use in multiple sectors and for multiple uses. While transitional periods and derogation periods will be essential to allow alternative materials to be assessed, designed and implemented where possible, consideration is also needed for businesses such as WMFTS who will need to conduct these investigative activities for many different products, across many different industries and uses within these periods. Sufficient time will be required to enable businesses such as WMFTS to effectively research suitable alternative materials for all affected products.  Request for exemption There is a shortage of data to demonstrate the amount of hazardous PFAS generated from manufacture (when using non-PFAS polymerisation aids), in-use and end-of-life cycles for fluoropolymers. Appropriate restrictions should still be placed on hazardous PFAS, but there is the opportunity to introduce emission restrictions and reporting requirements of hazardous PFAS for the manufacture, use and end-of-life cycles for fluoropolymers and fluoropolymer products. Once this data is generated, a decision can be made on the safety of fluoropolymers and if restrictions are necessary. In addition, the comments and evidence that have been provided here and in the confidential attachment report, show that fluoropolymers are a key material to provide solutions for many applications. The materials that have been covered within this report are: • PTFE (Hose liners, seals, gaskets, diaphragms, pump components) • ePTFE (Tubing, tubing elements) • PVDF (Tubing, tubing elements, tubing assemblies, pump components, pump connectors, pump cartridges, pumpheads) • FKM (Gaskets, seals, O-rings, pumpheads, pump drives, nozzles, diaphragms, pump components) • TFM (Diaphragms) • Fluoropolymer oils and greases (PTFE, PFPE) These fluoropolymers are materials of low concern and do not pose a risk. In many cases these materials are utilised precisely because they are inert and do not break down in otherwise highly chemically aggressive environments. As such, these fluoropolymer materials do not pose a risk to human or animal health, or the environment. This group of substances should therefore be given a broad exemption within the PFAS proposal.  General comments ECHA have advised that the property of highest concern with PFAS is the very high persistence due to the very strong C-F bond, with PFAS being known as “forever chemicals”. For the applications that WMFTS products that contain fluoropolymers are required for, it is this very strong C-F bond that is critical to achieve the chemical, heat and mechanical resistance required for the application. Suitable alternative materials are not currently available for many applications, but if new materials can be developed, these will need to have the same very high persistence to achieve the required chemical, heat and mechanical resistance, resulting in the same high persistence challenges. Any newly developed alternative materials are also at risk of posing additional hazards causing regrettable substitutions. If fluoropolymer materials are restricted, a wide range of products critical to many industries may no longer be available. Where alternative materials can be developed, the significant costs of development, evaluation, validation and registration of these new materials will likely be passed onto the individual consumers, making medical treatment, energy and transport among others unfeasible for many people, significantly reducing quality of life for the majority of individuals. Fluoropolymers are also seen as key materials to achieve global sustainability goals. If fluoropolymers can no longer be used, our goals for working more efficiently and sustainably may not be possible. As fluoropolymers do not exhibit bioavailability, bioaccumulative or toxic characteristics, these materials themselves can be considered as polymers of low concern (PLC) (see A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers - Korzeniowski - 2023 - Integrated Environmental Assessment and Management - Wiley Online Library). Placing the focus of restrictions on the emissions of hazardous PFAS for the lifecycle of fluoropolymers including, manufacture, in-use and end-of-life cycles would control the impact to the environment, without the extensive development activities, costs and resources required to identify alternative materials (if this is possible) and significantly reduce the disruption to multiple industries and global economies. Fluoropolymers should therefore be given a broad exemption within the PFAS proposal. |
| Answer to specific info request 1:  Please see the confidential attachment report. |
| Answer to specific info request 2:  Please see the confidential attachment report. |
| Answer to specific info request 3:  Please see the confidential attachment report. |
| Answer to specific info request 4:  Please see the confidential attachment report. |
| Answer to specific info request 5:  Please see the confidential attachment report. |
| Answer to specific info request 6:  Please see the confidential attachment report. |
| Answer to specific info request 7:  Please see the confidential attachment report. |
| Answer to specific info request 8:  Please see the confidential attachment report. |
| Answer to specific info request 9:  Please see the confidential attachment report. |
| Answer to specific info request 10:  Please see the confidential attachment report. |

|  |  |  |
| --- | --- | --- |
| 3978 | Date:  2023/04/28 16:00  Content:  Baseline  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  GUIN TECHNOLOGY SRL  Org. country:  Italy | General Comments:  IN OUR OPINION IT IS NOT CORRECT CONSIDERING PTFE DANGEROUS LIKE PFAS WITH SHORTER CHAIN...PTFE IS NOT A DANGEROUS MATERIAL , IF YOU THINK THAT IT IS USED ALSO IN FOOD SECTOR AND IN CONTACT WITH WATER IT IS ABSOURD THAT IT WILL BE FORBIDDEN... IF YOU WILL STOP PTFE , WE WILL CLOSE 90% OF OUR PRODUCTION..WE HAVE 62 WORKERS THAT WE WILL DISMISS |
| Answer to specific info request 1:  WE ARE PRODUCER OF SEMIFINISHED AND FINISHED PRODUCTS IN PURE AND FILLED PTFE..OUT PARTS HAVE BEEN USED IN SEVERAL SECTORS ( CHEMICAL ,PETROCHEMICAL, VALVES , AERODINAMIC , VALVES, COCKS ,...PTFE IS A MATERIAL THAT CAN BE USED IN SEVERAL COMPANIES |
| Answer to specific info request 4:  WE RECYCLE PTFE PARTS AND SCRAPS ..THESE CAN BE USED IN THE EXTRUSION .., |
| Answer to specific info request 8:  IF PTFE WILL BE STOPPED , IT CAUSE A LOT OF PROBLEMS TO US..AND ALSO TO THE SEVERAL WORKERS WORK IN GUIN TECHNOLOGY SRL |

|  |  |  |
| --- | --- | --- |
| 3979 | Date:  2023/04/28 18:56  Content:  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SHPP B.V.  Org. country:  Netherlands  Attachment:    <redacted> | Answer to specific info request 6:  Please find the answer to this question in the confidential attachment to this contribution and Executive summary as non-confidential attachment. |

|  |  |  |
| --- | --- | --- |
| 3980 | Date:  2023/04/28 19:03  Content:  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SHPP B.V.  Org. country:  Netherlands  Attachment:    <redacted> | Answer to specific info request 6:  Please find the answer to this question in the confidential attachment to this contribution and an Executive Summary in the Non-Confidential Attachment. |

|  |  |  |
| --- | --- | --- |
| 3981 | Date:  2023/04/28 19:07  Content:  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SHPP B.V.  Org. country:  Netherlands  Attachment:    <redacted> | Answer to specific info request 6:  Please find the answer to this question in the confidential attachment to this contribution and an Executive Summary in the Non-Confidential Attachment. |

|  |  |  |
| --- | --- | --- |
| 3982 | Date:  2023/04/28 23:48  Content:  Scope or restriction option analysis  Environmental emissions  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Academic institution  Org. name:  Deutsche Ophthalmologische Gesellschaft (DOG)  Org. country:  Germany  Attachment: | General Comments:  The annual rate of vitreoretinal surgeries in Europe is about 300 thousand. Postoperatively, perfluorodecaline as well as perfluoroctane are burned together with the clinical waste and fully destroyed according to Annex XV Restriction Report. |
| Answer to specific info request 1:  I refer to the letter attached. |
| Answer to specific info request 3:  I refer to the letter attached. |
| Answer to specific info request 6:  I refer to the letter attached. |
| Answer to specific info request 7:  I refer to the letter attached. There is no alternative. |
| Answer to specific info request 8:  Patient health, public health. I refer to the comments in the letter attached. |

|  |  |  |
| --- | --- | --- |
| 3983 | Date:  2023/05/01 19:12  Content:  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  InterApp AG  Org. country:  Switzerland | General Comments:  We produce butterfly valves and use fluoropolymers (PTFE, PFA, FKM and ECTFE) as corrosion protection material (disc overmoulding and lining) and without fluoropolymers, our butterfly valves cannot be used in the industries where are due to (chemical, mining, pulp and paper, desalination, semiconductor, ...) |
| Answer to specific info request 1:  Other coating applications (valve lining for corrosion resistance, high purity, non adhesive characteristics) |
| Answer to specific info request 5:  11,5 tons of fluoropolymers are used for the lining of our valves (PTFE and PFA) |
| Answer to specific info request 6:  a. Annual tonnage 11.5 tons b. Key functions why PFAS: corrosion resistance, high purity, non adhesive characteristics c. +/- 15 similar companies as we are would be affected by the ban of fluoropolymers d. No alternative known by today e. As users of fluoropolymers we buy, we rely on companies like Chemour, Solvay, etc. f. As users of fluoropolymers we buy, we rely on companies like Chemour, Solvay, etc. g. Up to 100 % loss of business, means 180 employees for InterApp group; on a sector level, thousands of employees lose their jobs; an then all the industries to which we could not supply our products for their use (chemical, mining, pulp & paper, etc.) |
| Answer to specific info request 7:  Today there is no alternative to fluoropolymers used in the valve industry and a ban would lead to company closures and unemployment. |
| Answer to specific info request 8:  For the applications we supply our valves to, there are no real alternative materials available to fluoropolymers, when it comes to corrosion resistance (e.g. chemical and mining industry) and high purity (semiconductor industry). Real life field applications have shown that only fluoropolymers work in certain applications. |

|  |  |  |
| --- | --- | --- |
| 3984 | Date:  2023/05/02 11:27  Content:  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  ACEM- The motorcycle industry in Europe  Org. country:  Belgium  Attachment:  <redacted> | General Comments:  As part of its ordinary working process, ACEM teamed up and aligned with ACEA (European Automotive Manufacturers Association) to express concerns on this restriction which could have severe implications in terms of safety, durability, electrification, fuel economy and CO2 reduction technologies as well as hampering developments of future initiatives due to its broad range of critical applications for our industry. Fluoropolymers in motorcycles are used in various components due to their characteristics of lubrication, electrical insulation, frictional properties, dielectric properties, flame retardancy, thermal stability, heat resistance, water and oil repellency. The industry addressed the possibility of replacing FP in products: - changing the tubing from fluorine to aromatic nylon tubing, - the fuel storage from fluorine to H-NB - the oil seal from fluorine to another type of rubber. However, due to low heat resistance, inability to meet fuel permeability and low fuel oil resistance, the alternatives have not met the quality standards and could not replace currently used materials. Substitutes for these materials are not available for all technical applications and material changes may result in risks like functional losses ( e.g. fuel efficiency, noise, liquid resistance/permeation), vulnerabilities, unsafe operation, increased wear, environmental impact (e.g. exhaust gas emission, oil releases, hydrocarbon) and more frequent need to change parts which will lead to an increase of discarded parts and a higher consumption of raw materials. In general, it can be said that at the time of writing there is no viable alternative all applications and that to research, develop and test new compounds a lead time of 15 years is the minimum necessary. Further to the necessary lead time, an indefinite derogation for legacy spare parts needs to be addressed. Without the requested derogation, the supply of legacy spare parts will be severely compromised, which is in strong contradiction to the overall strategic goals of the circular economy. We have a responsibility to consumers to support the longevity of their current vehicles by ensuring that these products can be serviced, repaired, and maintained in such a manner as to not be detrimental to their function, safety, and reliability. Extending the lifetime of a vehicle is essential to reducing costs for consumers, as well as conserving natural resources and energy. Thank you in advance for considering our comments as part of your assessment. We will further investigate required information and provide data within the current consultation period, however, please inform us should you have any questions or requests in the meantime. Finally, we would like to stress how, at this stage, only general information on applications, substances, and volumes can be formulated. We will further analyze this in the coming months, to be able to make more specific statements in ACEM’s final contribution. |

|  |  |  |
| --- | --- | --- |
| 3985 | Date:  2023/05/02 16:09  Content:  Scope or restriction option analysis  Information on alternatives  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  In-depth trials with alternative material thermoplastic "PEBAX" have shown that the dielectric strength in combination with biocompatibility cannot be replaced for applications in high-frequency surgery. Possible substitute materials could not be successfully qualified. |
| Answer to specific info request 1:  Tubes and catheters dielectric strength and temperature resistance in combination with biocompatibility for applications in high-frequency surgery, cannot be replaced with alternative materials |
| Answer to specific info request 4:  These are single use products that cannot be recycled after use in an operation. Hospital waste is disposed of by incineration as a thermal process. |
| Answer to specific info request 6:  e. In 2021, a start was made on qualifying alternative materials for tubes. Unfortunately, no material could be qualified as suitable. The trials took place over a period of 18 months. User trials were conducted on animal tissues under laboratory conditions with prototypes. g. As a result, surgical instruments would have to be taken off the market. Certain haemostatic minimally invasive operations in the gastro intestinal area would no longer be able to be offered in this way. |
| Answer to specific info request 7:  We are not aware of any alternative material with similar properties for our applications. |
| Answer to specific info request 8:  dielectric strength and temperature resistance in combination with biocompatibility for applications in high-frequency surgery, cannot be replaced with alternative materials. At present, it is not possible to estimate how long a changeover might take. There is no comparable material available on the world market with our performance characteristics. |

|  |  |  |
| --- | --- | --- |
| 3986 | Date:  2023/05/02 17:36  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Aalberts Surface Technologies GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  The documents contain business related informations. This can be in conflict with competitors in our business field. Thank you for taking care! | General Comments:  We can not see that all sectors of fluoropolymer applications are reflected in the dossier. We propose to create the sector of industrial applications. ​  Here within we request a derogation of fluoropolymers as a coating for the industrial industry sector as a whole. The sub - uses of fluoropolymers (PFA, PTFE, ETFE and related) are extremely broad and are mainly have links to other consumer or industry markets which than will be affected. For example, the coating of rollers to prevent stick of adhesives at high temperatures and production rates will impact the manufacturing of adhesive tapes, diapers and related products. Those productions will need to source from outside EU, no contribution to the worldwide usage, or relocated to none EU countries with socio-economic impact. ​  The general coating market seems to be small and is maybe 1 % of the total PFAS sector. However, it is the largest impact for productions sites across Europe. The coating industry is aware of development of alternatives. However, the timeline for the millions of parts and applications is with 18 month too short due to the fact, that today only extremely limited alternatives are available on the market as a proofed product, therefore we request a derogation.​  We as Aalberts Surface Technologies GmbH have 78 sites across mainland Europe, USA and China. We have 6000 employees and make a revenue of roughly 600 million Euro. Our customers come from all industry sectors. Along with our competitors we provide services to solve issues on corrosion, stick, antistick, vibrations, chemical resistance and heat resistance. This is where the fluoropolymer products are the solution compared to the alternatives which can not handle the combination of this five properties and fail or are not yet developed for this. |
| Answer to specific info request 2:  The products we use are produced by OEM manufacturers. We use roughly 50 tons in the Aalberts group of coatings containing fluoropolymers in a range of 5 to 60 weight percent of PFAS. Our product manufacturers like Chemours, PPG, Daikin, Weilburger and others will deliver the whole tonnages into the coating market. We identified more than 237 commercial products containing PFAS or need PFAS for the formulation. That shows the broad range of applications and customer needs. General waste is regulated strongly in Germany according to the Kreislaufwirtschaftsgesetz (KrWG). Waste is sorted into general and dangerous waste numbers. The coatings we apply fall under dangerous goods and are handled with special careunder designated waste key numbers. Our products are applied in very segregated areas by spray or dipping processes. During the application or production phase we emit mainly solvents and no polyfluorinated emissions to the air. The cabins have ventilations with filters which catch liquids, particles or none reacted products. The overspray which is not taken by the airstreams is solidifying on cardboard or foils in the cabinet or the rigid concrete floor. Those oversprays are broad to the general waste cycles in Germany and are burned or stored in specialized land fill. Liquid residues are collected and going to the special waste cycle and get thermally treated in waste plants. The material on the components for the industry is rigidized and cured in ovens. During use in production facilities during lifetime the coatings erode mainly, and emissions are banned locally in the productions sites and transferred into the waste stream cycles. After service life of the components those are sent back to us. The old coating is pyrolyzed and parts are getting recoated. Ther efore, the saving of resources for the manufacturing of the components for the chemical industry is high. Because of that those are metal based and mainly large and heavy. Some components are going to the metal scrap yards and will be recycled. In this process the PFAS containing coatingwill bepyrolyzed. Liquids form dipping and rinsing are sent to the wastewater purification system and the r esulting wastewater is transferred to the wastewater refurbish plant. Concentrations of critical substances are set as limit by the authorities. Concentrated bathes are part of the waste management according to the Kreislaufwirtschaftsgesetz(KrWG). Therefore, the end-of-life emissions arebelowa few kilograms per year in our sector. It is to be highlighted that fluoropolymers do not degrade, or they are not mobile, bio accumulative, or toxic and can be handled safely across the waste management and end-of-life cycle |
| Answer to specific info request 3:  During handling and production on our sites less than 1 % are emitted to the environment. The rest is cached or degraded fully to non PFAS in pyrolysis. Components which are landfilled are not leaching outdue to the rigid formand they arebound in other polymers. |
| Answer to specific info request 4:  No impact due to the regulations in the Kreislaufwirtschaftsgesetz (KrWG) in Germany and respective laws in the European states. The attempt to serve better the ban is to create a waste key for fluoropolymer containing waste to regulate directly thermal treatment and land fill requirements as this regulated for other critical substances as cadmium, blastingmedia or others. |
| Answer to specific info request 5:  The emissions to the environment will be very low and due to the millions of various applications the time for the development, testing and implementation will bemuch longer above The coating is used in large film manufacturing machines. The adhesion and temperature control properties of the fluoropolymers are tested for at least three to five years before going into service. As well as productions sites for the medical industry where the regulation MPG requires full clinical testing after change in the supply chain and products. This will require at least more than fiveyears and drives costs. Due to the broad customer base, we do have more than 20.000 articles to be reviewed on properties and application scenarios. Each of them are used for special scenarios and are not gathered together. For each at least four to five alternatives shall be tested in field tests over a period of month to years. In the past years we were driven by costs to omit or substitute fluoropolymer products. The final sum of products was finally not yet to substitute. Just the mass of articles and particular environments will not give the chance to find alternatives in the 18-month period and the time until EiF. Therefore, we propose: Ban with a transition period of 18 months and a 12-year derogation, because it could take a relatively long time (several years to several decades) to transition towards using alternatives that can achieve the same level of performance. Furthermore, given the relatively large (up to hundreds or thousands) number of individual products supplied in this sector, all with different specific formulations,this would be a complex undertaking needing sufficienttime. Continued R&D increases the chance that alternatives for the relevant applications will be identified in the next decade. |
| Answer to specific info request 6:  see a 20230502\_Industrial Applications Section 1 sub-uses |

|  |  |  |
| --- | --- | --- |
| 3987 | Date:  2023/05/02 17:59  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Aalberts Surface Technologies GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  Dear Team, the information is related to military apllications. Those are confidential at any time. Thank ou for taking care! | General Comments:  Due to the nature of military goods and the very long change and requalification periods as well as the hundred thousands of components and parts to be reevaluated we propose a derogation of 18 month + 12 years.​  ​Alternatives were tested only limited in the past due to frozen processes on the drawings. However, the below list gives a brief overview of the alternative materials. All of them combine that commercial products are not in the way accesable as they can substitute or partially substitute the properties of a fluorpolymer system. We estimate a timeframe of six to 12 years of research development and implementation of alternatives due to the technical readiness of the market products of TRL 3 to TRL 4 for the destinct appliaction. We do consider as well that polyfluorpolymers shall be not banned as well for this sector if it is shown by the users that it is save and the requirements of the EChA for safe use are fullfilled. |
| Answer to specific info request 1:  Please see attched confidential file. |
| Answer to specific info request 2:  Please see attched confidential file. |
| Answer to specific info request 3:  Please see attched confidential file. |
| Answer to specific info request 6:  Please see attched confidential file. |

|  |  |  |
| --- | --- | --- |
| 3988 | Date:  2023/05/02 18:36  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Aalberts Surface Technologies GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  The included information may enclose information which competitors can bring in a information position which is harmful fpor our small business. | General Comments:  The energy turn around is fully ongoing over the world. In the meantime the new technologies were invented and have had new chalenges for amterial properties. The field of the use of hydrogen or electric as energy for transport is rather young. Recent developments in the technology show that fluorpolymers are the only materials which can cope with this demanding properties.​  However, we see that research and development are strong in this field of energy for transportation, nut it took now five decades to develop the standard equioment and it will take another 12 to 15 years to develop a PFAS free alternative.​ ​ Therefore we ask for the highest exemption for all components used in the transportation sector.​  ​ |
| Answer to specific info request 1:  Transport​ - Use of PFASs in applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this proposed restriction​ Lubricants​ - Sector as a whole |
| Answer to specific info request 2:  please see attachment |
| Answer to specific info request 3:  please see attachment |
| Answer to specific info request 4:  please see attachment |
| Answer to specific info request 6:  Missing uses in compressors or related technical devices for the transport goods. All components that needs proper function and need to be yet available for the progress in carbon free transportaion fo e.g. haydrogen or electrical mobility. That includes as well the production of clean energy by electrolyser mebranes and sealant. to. a: roughly 20 tons per year for the various applications with fluorpolymer PFA and PTFE to b: high temperature, resistance and abrasion resistance at very high velocities as well as chemical resistance and fexibility. to c: at least three companies will ahve major impact including us with roughly 20 FTE and 1 to 2 mio. € revenue and upstram in the supply chain we estimate 1000 employees and 1 billion of revenue are depending on the use. to d. please see attachment for alternatives to e. the R&D did not start yet and is on TRL 1 a the moment. heavy investigation shall be made and will take at least 10 years from now to find equal or slightly worth alternatives. |

|  |  |  |
| --- | --- | --- |
| 3989 | Date:  2023/05/03 12:09  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  As a classic machine manufacturer, we are to be regarded as a "downstream user" with regard to the supply and application of substances and products containing PFAS. Our products (compressed air systems) are used in many areas, e.g. in the field of critical infrastructure such as the chem. Industry, pharmaceutical industry, food & medical supply. Other important sectors are: Automotive, mechanical engineering, heavy industry, mining, trades, aerospace technology, research & development. PFAS are present in many components in our products, the most important are: Lubricants & Coolants, Refrigerants, Coatings with sliding properties, Seals, Electrical cables , Electronic components and Coatings of filter media. From our point of view, a ban on the use of substances containing PFAS would have far-reaching effects, including the discontinuation of our production, since in many areas no fully adequate substitutes are yet available. Examples of this are Sliding coatings for breathing air compressors, special greases for high-temperature applications in oil-free compressed air production in the food & beverage industry, flame retardants in electrical cables and V-belts for compressed air production in the chemical and pharmaceutical industry. In the field of application of compressed air treatment by means of refrigerant dryers, alternative refrigerants may be available, but these alternative refrigerants entail further hazards. For example, they are often flammable or can produce an explosive mixture. The use of these alternative refrigerants severely limits the range of applications for our products. Equivalent substitute refrigerants are not yet available. Furthermore, a comprehensive PFAS ban would have global economic disadvantages for us (in relation to our customers and users) in almost all economic sectors of the EEA.  Statement: PFAS are, in our opinion, high-tech polymers that are irreplaceable in our products, as there are no equivalent alternatives for these properties. The PFAS are used in our products only in the inert state with the exception of the refrigerant dryers. An exposure to humans & the environment is therefore excluded. We therefore reject this undifferentiated approach to group regulation and urge the responsible government representatives of the European Union to reconsider the present PFAS ban proposal. |
| Answer to specific info request 1:  Food contact materials and packaging (Annex E.2.3) / (Industrial food and feed production, Plastic packaging & Other packaging applications) Medical devices (Annex E.2.9.) / (Packing of medical devices) Energy sector (Annex E.2.12.) Not only the auxiliaries, substances and products should be considered in this point, but also the machines that are needed for this are absolutely to be included in the considerations. Application of fluorinated gases (Annex E.2.8) / Refrigeration From our point of view, the application range of refrigeration technology in the compressed air application is poorly considered or not considered at all. Contrary to other applications in the compressed air sector, the use of alternative refrigerants cannot be implemented without risk. |
| Answer to specific info request 5:  Lubricants (Annex E.2.14.) In the last year, weh ad a turnover of about 750,000.00 Ltr. of Oil used in our machines. This value is a result of an internal analysis job of our controlling team. |
| Answer to specific info request 6:  The application in mechanical engineering is obviously not considered according to Annex A Table A1. PFAS are high-tech polymers that are irreplaceable in mechanical engineering, especially in compressed air generation / compressor construction, as there are no equivalent alternatives for these properties.b) Als Anwendungsbeispiel sind hier zu nennen: Gleitbeschichtungen für Atemluftkompressoren, Spezialfette für Hochtemperaturanwendungen bei der ölfreien Druckluftherstellung, Flammschutzhemmer in Elektrokabeln und Keilriemen. c) approx. 80,000 machine builders in Europe (source: Internet) d & e ) As the machine builder is to be classified as a "downstream user", a detailed statement is not possible here. f) i) The costs across Europe amount to a multi-digit million sum. ii) The substitution process will certainly take 20 years iii) he maintenance and servicing costs for the end customer will increase significantly, the efficiency of the machines will decrease, and energy consumption will rise as a result. g) In the event that substitution is not possible, the closure of individual companies could be the consequence in extreme cases. If substitution is possible, the maintenance effort for the user will increase significantly, the efficiency of the machines will decrease and the energy consumption will increase. |

|  |  |  |
| --- | --- | --- |
| 3990 | Date:  2023/05/03 13:10  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  PTFE seals are used in all sectors of the automotive sector. In some cases we cannot use any other material because of high temperatures / chemical environment / hard conditions. There is no alternative and a qualitative disadvantage and competitive disadvantage with all competitors who may use PTFE in the future. If PTFE is banned in the automotive sector, there is a high risk that different media could get into the environment. |

|  |  |  |
| --- | --- | --- |
| 3991 | Date:  2023/05/03 13:19  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  AllessaProduktion GmbH, WeylChem Höchst GmbH, WeylChem InnoTech GmbH  Org. country:  Germany  Attachment: | General Comments:  We submit a document in which the relevant topics are addressed. |
| Answer to specific info request 1:  We submit a document in which the relevant topics are addressed. |
| Answer to specific info request 2:  We submit a document in which the relevant topics are addressed. |
| Answer to specific info request 3:  We submit a document in which the relevant topics are addressed. |
| Answer to specific info request 5:  We submit a document in which the relevant topics are addressed. |
| Answer to specific info request 6:  We submit a document in which the relevant topics are addressed. |
| Answer to specific info request 8:  We submit a document in which the relevant topics are addressed. |

|  |  |  |
| --- | --- | --- |
| 3992 | Date:  2023/05/03 22:03  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The file contains information which is directly linked to product and customers. | General Comments:  please see attchment. |
| Answer to specific info request 1:  Medical industry, sector as a whole, use of fluorpolymers in components for medical device on of near body which si under european medical or any other regulation. |
| Answer to specific info request 2:  in the attachment. |
| Answer to specific info request 3:  in the attachment. |
| Answer to specific info request 4:  in the attachment. |
| Answer to specific info request 6:  in the attachment. |
| Answer to specific info request 7:  in the attachment. |

|  |  |  |
| --- | --- | --- |
| 3993 | Date:  2023/05/04 11:02  Content:  Scope or restriction option analysis  Environmental emissions  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Filtec W Hermanns GmbH  Org. country:  Germany | General Comments:  The impact for banning Fluropolymers (PTFE ) in the sectors technical textiles, energy sector and architectural membranes would lead to a decrease of lifetime of the used textiles since almost all substitutes for PTFE have a smaller range of resilience in acidic and caustic environments. This would also increase waste since the same PTFE textile could be used again if the substances for filtration is changed. In addition its inherent UV resistance makes it a perfect fit for membranes which should last for a very long time. All other materials decompose after a certain time under UV radiation. This leads to less waste. Also due to disposal at a special facility the release of toxic residual substances can be reduced. PTFE is widely used in technical textiles for different filtration usages. Finding a suitable alternative material that provides the same level of performance is challenging since the range of applications is always smaller then with PTFE. The innertness classifies this Fluropolymer as one with a much lower environmental concern than a lot of other PFAS substances. Therefore there should be an exemption for this Fluropolymer. |
| Answer to specific info request 1:  technical textiles, energy sector and architectural membranes |

|  |  |  |
| --- | --- | --- |
| 3994 | Date:  2023/05/04 11:24  Content:  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Netherlands  Company name confidential:  Yes | General Comments:  As an ozone manufacturer, we rely heavily on the use of PFAS (PTFE, FEP). This is used in our industry as a sealing material. But also for hoses to transport ozone (gas). Other materials have a limited life when used with ozone. So there are no good alternatives! |
| Answer to specific info request 6:  The only materials with a good resistance against ozone are PFAS materials like PTFE and FEP. Although the sector uses a limited amount of this material, the material is very important for the sector. A: unknown B: Only material resistant to ozone and suitable for gaskets and tubing C: >250 manufacturers of ozone equipment in Europe. That doesn't include the users of ozone equipment which are ten's of thousand companies. D: No good alternatives are available. E: Unknown F: Not applicable G: See point C |

|  |  |  |
| --- | --- | --- |
| 3995 | Date:  2023/05/04 11:58  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | Answer to specific info request 6:  >10.000 sales articles in the automotive, heavy truck, ... which use of hoses and sealing ring with FKM (PFAS). Each new material has to be tested in the sales product (needs thounsand of hours and million of euros). Each change has to be documentated, communicated and could influence of safety relevant products. |

|  |  |  |
| --- | --- | --- |
| 3996 | Date:  2023/05/04 12:21  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment: | General Comments:  In the semiconductor industry in detail the polishing of wafers to a particular thickness strong acidic medias are used. To prevent leaching of foreign metals into the waivers a PFA or PTFE fluorpolymer is used on the equipment on various parts. The waiver industry uses long term qualifications for there system and fixed processes are used for more than five years before changing to recover the immense investments.  Therefore we propose to add semiconductor industry with the sub-use manufacturing devices to form waivers.  We do the coating of this components with PFA or PTFE and our socio economic impact is low compared to the downstream use of our components at the builder companies of the polishing machines and the companies doing the polishing for the known chip companies. We expect drawback on the the European chip industry and the export of the equipment to the Asian markets. |
| Answer to specific info request 1:  Semiconductor industries, Waiver production, manufacturing equipment to form and polish waivers |
| Answer to specific info request 2:  see attachment |
| Answer to specific info request 3:  see attchement |
| Answer to specific info request 4:  see attachment |
| Answer to specific info request 5:  see attachment |
| Answer to specific info request 6:  see attachment |

|  |  |  |
| --- | --- | --- |
| 3997 | Date:  2023/05/04 13:16  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Description of analytical methods  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Keeping company names and product results secret from competitors. | General Comments:  1. Scope or restriction options analysis - A ban on PTFE is not appropriate because PTFE is not hazardous in bonded form - PTFE consists exclusively of carbon and fluorine atoms - PTFE is a solid particle, does not dissolve in liquids, no evaporation of fluids possible - PTFE cannot be absorbed into the human body (verification certificates: USP Class VI / FDA); PTFE does not accumulate as a chemical in the environment - PTFE gaskets are an important and inherent part in many industries, such as chemical industry, food industry, pharmaceutical industry and due to their technical properties prevent the leakage of hazardous substances in production to the environment Technical properties of Fluoropolymers: - Fire resistant - Weather resistant - Temperature resistant - Chemical resistance - Wear resistance and low friction - Non-wetting & non-stick - Dielectric strength - Durability & long life  All PFAS must not be grouped together, but must be considered individually: Polymeric / Non-Polymeric Long chain / Short chain Solids / Liquids or Gases Non-mobile / Mobile Non-soluble / Soluble Non-Bioaccumulative / Bioaccumulative Non-toxic / Toxic   2. Hazard or exposure - Our PTFE gaskets should be excluded from the restriction proposal because they are safe and do not pose any risk - This is also proven by the following certificates and test reports: USP Class VI, FDA, EC 1935/2004, Reach/ RoHS  3. Environmental emissions - PTFE residues: 16 tons/year are fully recycled by converters (to secondary products, e.g. PTFE as filler for PA6) and raw material producers (decomposition to original state (monomers)) - Used PTFE gaskets can be disposed of in the residual waste; the residues are completely degraded in the waste incineration plants (incineration higher 850°C).  4. Description of analytical methods - TGA analysis from Mettler-Toledo showed that our material is 99.99% pure PTFE.  5. Information on alternatives Possible alternative gaskets: - Silicone, EPDM, TPE, NBR gaskets: Silicone gaskets do not have complete chemical resistance and are not resistant to aggressive acids, for example: EPDM is not resistant to petroleum, gasoline, diesel, kerosene and propane (gas); Their resistance is strongly dependent on temperature and pressure and thus cannot be used in critical applications - No alternative for chemical industry, as high temperatures prevail and aggressive substances are used - Many applications must be free of silicone  - Graphite gaskets: resistant to high temperatures and pressures, but contamination may occur during installation. No alternative for food and pharmaceutical industry  In addition, certain types of flanges are widely used in the industry by well-known end customers, such as Kremo-Flange, GRP-Flange and steel enamel flanges, for which only a reliable sealing with a PTFE gasket has proven successful so far. Without a suitable gasket, the flange connections cannot be put into operation safely and the TA-Luft law cannot be complied with; this leads to high emissions and thus does not contribute to environmental protection.  6. Information on benefits Negative benefits: - Environment: The ban on PTFE gaskets will increase the release of hazardous substances into the environment as the industrial flanges cannot be sealed properly; this will have a negative impact on the environment and human health - Economy: Industries will no longer have the possibility to seal their flanges according to the TA-Luft standard and will therefore not be able to operate their plants. There is a risk that key industries (raw material producers, gasket manufacturers, food and pharmaceutical industries, chemical industry) in Europe will have to close down and that there will be an exodus. This causes enormous economic damage as well as a loss of technology in Europe. This in turn leads to a dependence on third countries.  7. Other socio economic analysis (SEA) issue - Ban on PTFE gaskets leads to closure of our company's site; this directly results in job losses for all employees - We are specialized exclusively in the production of PTFE seals (machines as well as employees) - The closure of the company also has a direct impact on suppliers (economic losses and threat of closure).  8. Transitional period - We cannot implement equivalent or better alternatives within a transition period. A ban directly means the closure of our business. |

|  |  |  |
| --- | --- | --- |
| 3998 | Date:  2023/05/04 13:25  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Description of analytical methods  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Customers/ Competitors shouldn´t get knowledge of our submissions | General Comments:  Since fluoropolymers and fluoroelastomers are classified as substances of low concern under the OECD criteria, many experts believe that they should be exempt from PFAS restrictions, at least for all types of industrial applications.  Generally, also our company want to take the environmental idea into account! As we are manufacturer of electromagnetic devices for all kind of industries and applications (industrial, energy, automotive, aerospace, medical, subsea, offshore, textile, hydraulic and pneumatic ...) we use lots of function and safety relevant articles/materials made of fluoropolymers/fluoroelastomers contenting PFAS, but we are not involved directly with the chemical substance PFAS. Depending from the function and safety relevant applications we use all the positive characteristics of the used fluoropolymer materials as there are low friction, durability, heat resistance, excellent chemical resistance, low permeation….  Following aspects if we are challenged to find PFAS-free alternatives, especially fluoropolymers/fluoroelastomers due to their potential banning:  As we develop each of our numerous devices especially for individual applications and customers, it would be very difficult to release alternative PFAS-free materials, even if they seem to become adequate. That means, we have no subject to technical changes, every change has to be released by the customers with which we usually have a very restrictive “Quality Assurance Agreement”. Time consuming design change efforts and resulting release tests according to customer specific test procedures and also time consuming field tests by our customers would be necessary for adequate releases with unforeseeable socio-economic costs.  Also quality and endurance impairments are expected accompanied by a significant surplus loss and unforeseeable threatened jobs.  In the event of a ban or restriction of materials due to PFAS, we and probably all industries without exception would be confronted with unreasonable development work for each of the very numerous applications. Instead, it would be urgently recommended that any PFAS bans or restrictive regulations be replaced by requirements on the part of PFA manufacturers and processors that ensure safe processing of PFAS substances that is not harmful to health and environment.  Since we are not producing the used PFAS contenting materials by ourselves, we even don´t know, which of the materials/ parts we use are contenting PFAS. Even most of our suppliers can not answer individually to our required comments in this subject. They inform that they are currently in preparation for a general comment and they also want to participate ECHa´s PFAS-consultation. So far, only feedback from suppliers who have been requested to comment, stating that they do not supply any articles with PFAS. So, the articles and materials containing PFAS used by us are not recognizable as containing PFAS as long as we do not receive corresponding information from our suppliers (e.g. preferably in the form of CAS numbers in the safety data sheets provided). Not even the safety data sheet of a grease in question contains a reference to PFAS contained therein.  Therefore, we cannot fully estimate at this time which articles would need to be substituted and to what extent, what cost increases and validation costs would be involved, and to what extent there would be an associated loss of jobs and revenue.  Cost-effective changes of constructive natures (e.g. replacing O-ring sealings with seal weldings) are mostly contrary due to the increasing requirements regarding repairability and recycling.  Since fluorinated materials are usually very expensive compared to fluorine-free materials, they were selected at the beginning of each development process after careful consideration and cannot be easily replaced, since alternatives usually cannot fully cover the required diverse and unique performance characteristics. Not as good as possible, but as good as necessary is always the motto.  Uncertainties regarding future restrictions/bannings are already affecting new developments and necessary investments. Hoarding purchases and resulting material availability problems in the event of hasty material discontinuations can be expected with the result that safety relevant devices cannot be delivered anymore/in time. |
| Answer to specific info request 1:  As we are manufacturer of electromagnetic devices for all kind of industries and applications (industrial, energy, automotive, aerospace, medical, subsea, offshore, textile, hydraulic and pneumatic ...) we use lots of function and safety relevant articles/endproducts made of fluoropolymers/fluoroelastomers contenting PFAS, but we are not involved directly with the chemical substance PFAS (processing). |
| Answer to specific info request 2:  During manufacturing phase in our house and the using phase the expected PFAS emissions are estimated to be very negligible, as we have negligible waste. |
| Answer to specific info request 3:  At the end-of-life our devices usually are electro scrap with expectable negligible PFAS emissions. |
| Answer to specific info request 6:  See SECTION III. Non-confidential comments |
| Answer to specific info request 7:  See SECTION III. Non-confidential comments |
| Answer to specific info request 8:  See SECTION III. Non-confidential comments |

|  |  |  |
| --- | --- | --- |
| 3999 | Date:  2023/05/04 13:57  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  The topic should be viewed in a differentiated manner. The different PFAS are not equally harmful to health and the environment. Our PTFE-based sliding elements for oil-free piston compressors, for example, also have approval for products used in medical applications (respirators) and dental technology (compressed air-driven dental drills). They make it possible to avoid the use of oil, which is also not without risks, e.g. in the area of fire protection and contamination in the event of accidents (environmental risk and drink water pollution). Here, the oil-free compressed air industry makes a valuable contribution to minimizing the risks associated with environmentally friendly means of transport, such as buses and trains. For low-maintenance, oil-free compressed air compressors, there are currently no alternatives to PTFE-based sliding elements, as PTFE has the smallest coefficient of friction and the high temperature resistance required for this application. |
| Answer to specific info request 1:  1.) Use sector „Applicants of fluorinated gases” with sub-uses “Refrigeration: Use of product oil free compressor at customer project with piston sleeve, PTFE in the grease of the bearings and FKM seals for cooling of cargo container on transport ships worldwide 2.) Use sector „Petroleum and mining“: Use of product vapour recovery pump with PTFE, with piston sleeve , radial shaft seal and seals for petrol stations worldwide 3.) Use sector „Transport“: Use of products oil free air compressors (piston ring and piston guide band) with PTFE, with piston sleeve, grease of the bearings and gaskets, made from FKM or FFKM and sealing washer in the bearing for use for main air and auxiliary air for the use in E-Buses, Trains and E-Trucks worldwide. Safety Valve with PTFE sealing) to make sure that the product is running in safety conditions (protect the system against overpressure) 4.) Use sector „Medical devices“ with sub-uses “Diagnostic laboratory testing”: Use of laboratory compressor station with PTFE, with piston sleeve and seals with FKM 5.) Use sector „Medical“ with sub-uses „Rigid gas permeable (RGP) contact lenses and ophthalmic lenses: Use of a laboratory compressor with PTFE, with piston sleeve and seals with FKM 6.) Use sector „Energy sector“: Use of a pump with ATEX Certification for use in explosive atmospheres with piston sleeve and seals for petrol stations, for cogeneration units and biogas plants worldwide 7.) Use sector „Lubricants“: Use of the components piston sleeve |
| Answer to specific info request 2:  1.) Manufacturing phase: In the manufacturing phase we have no rubbish or anything else. Only assembly in the production line. 2.) Use phase: Low emissions of dust, which is non-toxic and environmental friendly certified 3.) End-of-life phase: At 5 kg PTFE per year, we will get in thermal recycling 2.5 kg C02 and an electrical power output of 3 kWh |
| Answer to specific info request 3:  Sleeve and seals will reach 5 kg/ year. The disposal will be done by a special waste company. They do material and termal recycling. |
| Answer to specific info request 4:  Recycling by a special waste company. The special waste company fulfills the European recycling laws and requirements. |
| Answer to specific info request 5:  No emissions without a combustion process. In controlled combustion, PTFE is mainly converted into carbon dioxide and hydrogen fluoride, which is converted into non-toxic fluorspar by filter systems in waste incineration plants with European standards. Oxides of the respective fillers may also be formed. Waste of pure PTFE / TFM from production (chips or similar) is fed into a recycling process. Recyclates are produced from this, which now have very good material properties. |
| Answer to specific info request 6:  a.) The annual tonnage and emissions associated with the use of fluoropolymers can vary depending on the specific polymer and its applications. Here are a few examples: 1. Polytetrafluoroethylene (PTFE): PTFE is commonly used as a non-stick coating for cookware, as well as in industrial applications such as chemical processing equipment and electrical insulation. According to a report by the European Chemicals Agency, the estimated annual production volume of PTFE in Europe is between 10,000 and 100,000 tonnes per year. The emissions associated with PTFE production and use can include greenhouse gases and fluorinated compounds, which are known to have high global warming potential. 2. Perfluoroalkoxy (PFA): PFA is similar to PTFE but offers better mechanical properties and is often used in applications where high temperatures and pressures are involved. The annual production volume of PFA is lower than that of PTFE, with estimates ranging from 1,000 to 10,000 tonnes per year in Europe. Like PTFE, PFA production and use can result in greenhouse gas emissions and fluorinated compounds. 3. Fluorinated Ethylene Propylene (FEP): FEP is a fluoropolymer that is commonly used as a non-stick coating for films and tapes. The annual production volume of FEP is estimated to be between 1,000 and 10,000 tonnes per year in Europe. The emissions associated with FEP production and use can include greenhouse gases and fluorinated compounds. Overall, the annual tonnage and emissions associated with fluoropolymers can be significant, especially in high-volume applications such as cookware and industrial equipment. Efforts are underway to reduce the environmental impact of fluoropolymers through improved manufacturing processes and the development of new materials. Oil free compressors, like compressors from Dürr Technik, have a value of 0,6 tonnes of PTFE. b.) Chemical Resistance: Fluoropolymers such as PTFE (polytetrafluoroethylene) and FEP (fluorinated ethylene propylene) offer excellent chemical resistance against acids, bases, and other corrosive substances. They are commonly used in chemical processing equipment, laboratory apparatus, and in the production of semiconductor materials. 1. High Temperature Resistance: Fluoropolymers can withstand high temperatures without degradation, making them ideal for use in high-temperature environments. PTFE, for example, can withstand temperatures up to 260°C, while PFA (perfluoroalkoxy) can withstand temperatures up to 260°C. 2. Low Coefficient of Friction: Fluoropolymers have a low coefficient of friction, making them highly effective as non-stick coatings. PTFE is commonly used as a non-stick coating for cookware, while FEP and PFA are used in the production of non-stick tapes and films. 3. Electrical Insulation: Fluoropolymers are also excellent electrical insulators due to their high dielectric strength and low dielectric constant. They are commonly used in electrical cables, wire coatings, and electronic components. 4. Biocompatibility: Certain fluoropolymers, such as ETFE (ethylene tetrafluoroethylene), are biocompatible and can be used in medical applications, including implants and surgical instruments. Chemical resistance, high temperature resistance, low coefficient of friction and biocompability are very important functions for Dürr Technik products. c.) The forbidden of PTFE, FKM have a negative impact to all Dürr Technik supplierer and customer d.) Consideration of alternative solutions from the last 50 years. The constructive designs of the products are for the use of PTFE especially of the thermic properties and chemical resistance. Other solutions like oil lubricated compressors as alternative solutions with more maintenance on the products, more waste disposal effort, lower lifetime and the problem, that oil lubricated compressors will not be accepted by the customer because of high effort. e.) Contracts available for the railway industry, biogas plants industry for more than 30 years. Long term frame contracts are made with manufacturers of electric buses and electric trucks in order to push the worldwide e mobility. Every product change needs a special confirmation from the customer inclusive complex approval process (internal tests, external tests with test labs, involvement of Notified Bodies) f.) anual costs of approx. 15% of the yearly turnover because the whole Dürr Technik product range needs to be redisigned or substituted. Mínimum 7-10 years for development of new products and the risk of non acceptance of our customer side and also in the approval process with Notified Bodies. g.) Loss of the business model of Dürr Technik and also loss of activities in the market. Loss of the customer and on the end of the business field. This means no products and/ or applications on the market (tranportation, e-mobility, medical, industrial and energy sector). Therefore, less tax for Germany and also unemployeed people. In many ways, no alternative available and a forbidden with hugh negative impact to the market. |
| Answer to specific info request 7:  Today, there are no other materials or alternatives available which fulfills the chemical resistance, high temperature resistance, low coefficient of friction and biocompability the very important functions for Dürr Technik products. With the experience of Dürr Technik in the field of material use (basic/ fundamental research) there are no alternatives on the market in the future instead of PTFE and FKM available with the positive effects for the products (chemical resistance, high temperature resistance, low coefficient of friction and biocompability) |
| Answer to specific info request 8:  While fluoropolymers offer unique properties that make them highly useful for certain applications, there are some concerns about their environmental impact and safety. As a result, there is growing interest in finding alternatives to fluoropolymers. Here are a few possible alternatives: Silicone: Silicone is a synthetic polymer that is heat-resistant and has low chemical reactivity. It can be used in applications that require similar properties to fluoropolymers, such as in cookware, medical implants, and electrical insulation. Bio-based Polymers: Bio-based polymers, such as polylactic acid (PLA) and polyhydroxyalkanoates (PHAs), are derived from renewable resources and are biodegradable. They can be used in applications where fluoropolymers are currently used, such as in packaging, textiles, and biomedical devices. Ceramics: Ceramics offer high thermal resistance and low thermal expansion, making them suitable for high-temperature applications. They are also biocompatible and can be used in medical implants. Natural Materials: Natural materials, such as cotton, wool, and silk, can be used as alternatives to fluoropolymers in textiles and clothing. They offer natural breathability and can be biodegradable. Thermoplastic Polyurethane (TPU): TPU is a thermoplastic elastomer that offers good chemical resistance and elasticity. It can be used in applications where flexibility and durability are required, such as in medical devices and sports equipment. The mayor benefit of fluorpolymers is the combination of these specific caracteristics which are required for many products used in highly sophisticated technological applications. Available alternatives on the market may not offer all of the required properties as fluoropolymers (chemical resistance, high temperature resistance, low coefficient of friction and biocompability). The fluorpolymers may be suitable for certain applications where environmental impact and safety are concerns. If fluoropolymers were to be forbidden, there would likely be significant socio-economic impacts, as they are widely used in many industries, including chemical processing, electronics, cookware, and textiles. Here are a few potential impacts: 1. Increased Costs: Fluoropolymers are often used in high-performance applications where their unique properties are essential. Finding alternatives that offer similar properties may be more expensive, resulting in increased costs for manufacturers and consumers. 2. Job Losses: Many industries that rely on fluoropolymers would be affected by a ban. This would result in job losses for workers in these industries, including those involved in manufacturing, research and development, sales, marketing and all the other departments in the companies. 3. Product Innovation: Fluoropolymers have enabled the development of many high-performance products. A ban on fluoropolymers would likely require companies to invest in research and development, hopefully to find new materials that offer similar properties. This would slow down product innovation in many industries, like e mobility, low maintenance for trains, hazardous hydrogen fuel stations and medical air applications (for example in hospitals) Overall, a ban of fluoropolymers would have significant negative socio-economic impacts. Today, Dürr Technik use the substances PTFE and FKM only in case of high requirements in combination of chemical resistance, high temperature resistance, low coefficient of friction and biocompability. |

|  |  |  |
| --- | --- | --- |
| 4000 | Date:  2023/05/04 15:56  Content:  Hazard or exposure  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  Privacy statement: Includes information on volumes of catalyst and products manufactured with, production know-how, number and type of products potentially affected, turnover, and this is confidential business information. | Answer to specific info request 6:  We would like to provide specific information on the use of PFAS in the chemical industry (chemicals synthesis). See two attached documents (one non-confidential version and one confidential version). |

|  |  |  |
| --- | --- | --- |
| 4001 | Date:  2023/05/04 17:29  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes | Answer to specific info request 1:  Lubricants (Annex E.2.14) |
| Answer to specific info request 5:  Lubricant : Annual tonnage 2022 : Solvent carrier PFPE & PTFE = 6T ; PFPE = 37T ; PTFE=8T ; total PFAS= 51T 25% of uses it’s for high temperature condition (>180°C), in this case 50% of lubricants are evaporated in the atmosphere, so globally 6T |
| Answer to specific info request 6:  PFAS carrier solvents (CAS (EC No.) 422-270-2) are used to apply an imperceptible film of PFPE oil to optimise the use of the lubricant and reduce the amount of lubricant. They are also used to clean surfaces treated with PFPE lubricants. Annual tonnage: 6T All manufacturer of lubricant using PFAS dispersion in carrier solvent are impacted and around 55 of our customers mainly in automotive industry. No technical alternative actually, solution could be to not use this carrier so the concentration and viscosity of lubricant will be very high, and not possible to spread it in a thin film. |
| Answer to specific info request 7:  PTFE alternative proposed seems technically acceptable, but we must develop formulation with this new component, to be able to have a final product lubricant with the same technical performance, even if cost will be higher; and after we need time to validate all applications on different markets, especially automotive or aerospace will require a long time, over 2 years. So derogation for 5 years seems acceptable For PFPE, no alternative identified, no R&D program launched on our different suppliers. So derogation must be over 12 years |
| Answer to specific info request 8:  IKV produce lubricant for many different industries, and lubricants using FluoroPolymers represent 50% of its turnover Actually, the market have no solution to substitute PFAS ? as a lubricant, so if ECHA decide to stop using of PFAS, for IKV that mean a shutdown of certain product lines, with loss of sales, cost operation to plant resizing, and 50% of people fire . In automotive, our lubricant PFAS products are key, carmakers can't produce quality and safe vehicle if they have not these products. Same in aerospace, medical, oxygen, electronic. All PFAS product lubricants are critical: - for electronic, PFAS lubricants guarantee quality of contact, if not, consequences are default of mechatronic on vehicle, so safety of vehicle - in bearing, PFAS lubricants are non-flammable and guarantee to be use at high temperature, so all industry using high temperature in their process will stop their production: glass, metal,.. The specific performances expected by our customers: - the Automotive industry due to wide temperature range expected and chemical compatibility required in presence of plastics or elastomer contacts. - Low torque on wide service temperature induces Electrical Application. - OEM \_ Vacuum pump \_ Compliance with gas or oxygen liquid under pressure (avoiding any explosion). - OEM for elastomer and plastic chemical inertia. Food Industry Compliance with NSF HX1 when high temperatures are required like bakery… - For all industries the best resistance to high temperature allowing extended life of equipment, reduction of maintenance, productivity and a reduction of energy power consumption. So, in automotive and other high-tech industry (aerospace, medical,..), the market have no solution to substitute PFAS, so if ECHA decide to stop using of PFAS, Customer will continue to use PFAS for their product/business , and will produce equipment out of EEA countries buying PFAS out of EEA Timing of validation, in case of one day market propose a solution: the longer approval time is for the BAM testing : 26 weeks. Regarding the NSF approval, depending on the formulation of the product at worst 2 months. For Automotive industry, process of validation starts from 6 months to 2 years. Could be longer if many projects of substitution must be conducted in the same time. |

|  |  |  |
| --- | --- | --- |
| 4002 | Date:  2023/05/04 17:53  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Description of analytical methods  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Berghof Products + Instruments GmbH  Org. country:  Germany | General Comments:  Scope of restriction: The definition of PFAS is too broad. It covers in particular Fluoropolymers which we regard as non-hazardous. (see Henry et al, Integrated Environmental Assessmenet and Management, Vol. 14 (3), 2018, 316-334; Korzeniowski et al, Integrated Environmental Assessment and Management, Vol 0(0), 2022, 1-30; F8Sale et al, ICRL, 1, 2022, 13-23.) Todays Fluuropolymers we´re using are free of polymerisation aids (surfactants) and mustn´t be restricted therefore. Especially as the scope of applications we´re covering with our products play a key role in the quality control of food, water, environment, pharma, cosmetics ... and thus enhances safety of humans.  Hazard or Exposure We source fluoropolymer components and use them without additional post-processing. All materials used are free from "Polymerisation Aids (surfactants)" and therefore employees are not at risk. All products are supplied to B2B customers only and used solely in scientific, chemical laboratories. They aren´t water soluble, not taken up by cells and therefore won´t spread into nature. see Henry et al, Integrated Environmental Assessmenet and Management, Vol. 14 (3), 2018, 316-334; Korzeniowski et al, Integrated Environmental Assessment and Management, Vol 0(0), 2022, 1-30; Sale et al, ICRL, 1, 2022, 13-23.)  Baseline: We source components made of below listed fluoropolymer and use them without additional post-processing. Total tonnage is approx. 8 tons / year. PTFE and TFM (modified PTFE) CAS No. 9002-84-0 (Polytetrafluorethylen) PFA 26655-00-5 (Polyfluroalkoxy) PVDF 24937-79-9 FEP 25067-11-2 (Polyfluor(ethylen-propylen) FKM/FPM 64706-30-5 (Fluorkautschuk) FFKM 26425-79-6 (Perfluorkautschuk)  Informations on alternatives: No PFAS free alternatives available that cover all usecases of the current system.  Information on benefits: universal chemical resistance to all kind of reagents high T-range of application up to 300°C Purity of the materials - avoidance of contaminations with metals Microwave transparency Hydrophobicity  Socio economic analysis: Microwave digestion systems are mainly used in quality control and public and contract testing laboratories (materials testing, chemistry, pharma, food, environment, electronics ...). E.g. Heavy metals in foodstuffs, waste/surface/drinking water, drugs or toys, monitoring of the RoHS directive in electrical appliances, etc. They are therefore necessary for the control and enforcement of corresponding legal regulations such as RoHS, REACH, Drinking Water Guideline, Environmental Law, Pharmaceutical Law, Directive 88/378EWG Safety of Toys, etc. If there were no derogations to be granted, we need to evaluate the new PFAS-free (not exisitng yet) to be in agreement with the existing qualtiy controll regulations. This additional application development will result in higher product prices. The process is controlled by means of a temperature sensor specifically developed for this application. It´s based on the optical properties of the microwave vessels (made of PTFE) in the near infrared (1-3µm, Patent No. 4412887). It´s unknown yet if alternative materials work with this temperturemeasurement concept. Lower performing materials will lead to poorer accuracy in such analysis bearing a potential risk for the society in general.  High-pressure reactors are mainly used in research and development (universities, chemistry, pharma, automotive, materials technology, food) but also in quality control or public and contract testing laboratories (materials testing, chemistry, pharma, food, environment, electronics ...). Examples of applications are investigations of material embrittlement under hydrogen overpressure, ageing of sealing materials, the production of zeolites, nanoparticles, catalysis research, etc. Finding alternatives for the full lining of high-pressure reactors made of PTFE will force us to redesign the high-pressure reactor interior, since the material properties (thermal expansion coefficients, notch stress, and other) will not be identical. Depending on severeness of the redesign, old products will not work with alternatives. Lower performing materials will hinder technological progress in these and other high tech areas.  This applies to many instruments used in chemical laboratories. Most of them use Fluoropolymers too due to their universal chemical resistance and high operation temperature. Examples: AAS, ICP-AES, ICP-MS, GC, HPLC, titrators, liquid handling systems, centrifuges, and many others more. Therefore we´re sure this is of broad interest for the whole range of laboratory equipment.  Transitional period Even with derogations coving our products and applications it´ll be challenging to susbstitute Fluoropolymers in our products. Transitional period needed is more than 10 years. Long-term chemical resistance to all kind of chemicals up to 300°C has to be assured for alternative materials. This requires time consuming testing and material evaluation processes.  Request for exemption: Due to the special design of our products and the unavailability of alternative materials, it is impossible to offer to our existing customers any alternative. A supply of spare parts and continued operation of the devices would therefore be impossible. Customers will need to buy completely new equipement. We plead therefore for a general exemption of Fluoropolymers from the group of PFAS or an derogation of more than 10 years for usage of Fluoropolymers in instruments for chemical laboratories. |

|  |  |  |
| --- | --- | --- |
| 4003 | Date:  2023/05/04 17:59  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Berghof Products + Instruments GmbH  Org. country:  Germany | Answer to specific info request 1:  Sector: Lubricants Sub-Use: Sector as a whole |
| Answer to specific info request 6:  a. We use PTFE paste and PTFE slide bearings as lubricants for threads sealing high pressure/temperature reactors up to 200bar & 300°C in chemical laboratories, and as chemically resistant fluoropolymer plain bearings for applications in magnetic stirrers in high pressure/temperature reactors up to 200bar & 300°C in chemical laboratories. We introduce < 50kg /year into EU market Polytetrafluorethylen PTFE 9002-84-0 b. greasing of threads and fast revolving stirring shafts (up to 2500rpm), avoidance of thread and shaft seizing universal chemical resistance to all kind of reagents high T-range of application up to 300°C c. All universities and public research institutions in the STEM sector Contract and public testing laboratories, R&D in chemistry, pharma, food, automotive engineering, materials engineering, mining ... Quality control labs in environment, food, chemistry, pharma, automotive engineering, materials engineering, ... Competing companies: approx. 10 in EU e. No PFAS free alternatives available that cover all usecases of the current system. MoS2 based greases may be applicable for certain but not all usecases Graphite bearings may be applicable for certain but not all usecases Alternatives are not as universally applicable as Fluoroplomers which cannot be susbstituted one-to-one, therefore. Application-specific solutions have to be developed and introduced into the markets. Users therefore need several devices and more operating know-how. Conclusion: There is no ready to use alternative avaílable and development of alternative solutions will take min. 8 years. We do not have the ressources to develop new materials but depend on suppliers in this respect. So at first, potential alternatives have to be found, extensivley tested with all kind of chemical reagents to assure. Thus, even with derogations coving our products and applications it´ll be challenging to susbstitute Fluoropolymers in our products for all usecases. Total estimated costs: 200.000 € g. A derogation is needed also to continue operation of the devices already in operation. Due to the special design of these systems, it is not possible to find alternatives that are compatible with them and could therefore be offered to existing customers as alternatives. A supply of spare parts and continued operation of the devices would therefore be impossible without an exemption. |
| Answer to specific info request 8:  The products are used in high-pressure reactors: High-pressure reactors are mainly used in research and development (universities, chemistry, pharma, automotive, materials technology, food) but also in quality control or public and contract testing laboratories (materials testing, chemistry, pharma, food, environment, electronics ...). Examples of applications are investigations of material embrittlement under hydrogen overpressure, ageing of sealing materials, the production of zeolites, nanoparticles, catalysis research, etc. Consequences, if no derogations are granted: a. Lower performing materials will hinder technological progress in these and other high tech areas. b. Impropper corrosion protection of pressure-bearing parts leads to a potential safety issue with the operation of our high-pressure reactors c. Additional application development will result in higher product prices. |

|  |  |  |
| --- | --- | --- |
| 4004 | Date:  2023/05/04 18:04  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Berghof Products + Instruments GmbH  Org. country:  Germany | Answer to specific info request 1:  Sector: Medical Devices Sub-Use: Diagnostic laboratory testing Altough these products are also used in diagnistic labs (e.g. Forensic labs, etc.) the main range of application (>90%) is within general analytical laboratories (e.g. Environmental labs, Food & Material control, Pharma, Chemistry, Mining, ...). Therefore, we would feel more compfortable with a new derogation for this usecase named for example ´Fluoropolymers for use in laboratory equipment" |
| Answer to specific info request 6:  a. Microwave heated pressure vessels for acid digestions with conc. mineral acids (HNO3, HCl, HF, H2SO4, H3PO4) up to 300°C and 100bar. The vessels are used for sample preparation in trace analysis of cations in any solid or liquid samples. E.g. Heavy metals in foodstuffs, waste/surface/drinking water, drugs or toys, monitoring of the RoHS directive in electrical appliances, etc. They are therefore necessary for the control and enforcement of corresponding legal regulations such as RoHS, REACH, Drinking Water Guideline, Environmental Law, Pharmaceutical Law, Directive 88/378EWG Safety of Toys, ..... Applications follow international DIN, EN, ISO etc. standards or regulations like Ph.EUR. etc. The vessels must be absolutely metal-free to avoid contamination of the samples even in the sub-ppb range. In addition, the vessels must be microwave-transparent to allow microwave heating. We introduce approx 2.500 kg / year into EU market Polytetrafluorethylen PTFE 9002-84-0 Polyfluoralokoxy PFA 26655-00-5 b. universal chemical resistance to all kind of reagents high T-range of application up to 300°C Purity of the materials - avoidance of contaminations with metals Microwave transparency Hydrophobicity c. All universities and public research institutions in the STEM sector Contract and public testing laboratories, R&D in chemistry, pharma, food, automotive engineering, materials engineering, mining ... Quality control labs in environment, food, chemistry, pharma, automotive engineering, materials engineering, ... Competing companies: approx. 10 in EU e. No PFAS free alternatives available that cover all usecases of the current system. Partial substitution by Quartz glass vessel with pressure-resistant sealing caps made of Fluoroploymers may be possibel to reduce volume of Fluoropolymers used per year. However,This isn´t useable with applications using Hydrofluoric Acid. Approx. 20-25% of the applications require addition of Hydrofluoric acid. There is no alternative material for applications with hydrofluoric acid (HF). Metal-free, microwave transparent, termperature and chemical resistant sealing caps for quartz vessels must then be made of Fluoropolymers again. There is no alternative material for sealing under such conditions available as yet. The process is controlled by means of a temperature sensor specifically developed for this application. It´s based on the optical properties of the microwave vessels (made of PTFE) in the near infrared (1-3µm, Patent No. 4412887). It´s unknown yet if alternative materials work with this temperturemeasurement concept. Therefore, completely new technologies have to be developed Conclusion: There is no ready to use alternative avaílable and development of alternative solutions will take min. 12 years. Completely new technology for sample digestion in analytical chemsitry has to be developed, extensively tested, validated, entered into standards (DIN, EN, ISO) before it could be marketed successfully. Whereby it is unclear how this could be done as yet. Thus, even with derogations coving our products and applications it´ll be challenging to susbstitute Fluoropolymers in our products for all usecases. Total estimated costs: 3. Mio. € g. A derogation is needed also to continue operation of the devices already in operation. Due to the special design of these vessels, it is not possible to find alternatives that are compatible with them and could therefore be offered to existing customers as alternatives. A supply of spare parts and continued operation of the devices would therefore be impossible without an exemption. |
| Answer to specific info request 8:  Laboratory microwave systems are mainly used in quality control and public and contract testing laboratories (materials testing, chemistry, pharma, food, environment, electronics ...). E.g. Heavy metals in foodstuffs, waste/surface/drinking water, drugs or toys, monitoring of the RoHS directive in electrical appliances, etc. They are therefore necessary for the control and enforcement of corresponding legal regulations such as RoHS, REACH, Drinking Water Guideline, Environmental Law, Pharmaceutical Law, Directive 88/378EWG Safety of Toys, etc. If there were no derogations to be granted, we need to evaluate a new PFAS-free (not exisitng yet) technology to be in agreement with the existing quality controll regulations. This applies to many instruments used in chemical laboratories. Most of them use Fluoropolymers too due to their universal chemical resistance and high operation temperature. Examples: AAS, ICP-AES, ICP-MS, GC, HPLC, titrators, liquid handling systems, centrifuges, and many others more. Therefore we´re sure this is of broad interest for the whole range of laboratory equipment. Consequences, if no derogations are granted: a. Application must be developed newly what will result in higher product prices. b. Lab Microwave Systems are necessary for the control and enforcement of corresponding legal regulations such as Food, RoHS, REACH, Drinking Water Guideline, Environmental Law, Pharmaceutical Law, Directive 88/378EWG Safety of Toys, ..... c. Lower performing materials will lead to poorer accuracy in such analysis bearing a potential risk for the society in general. d. Impropper corrosion protection of pressure-bearing parts leads to a potential safety issue with the operation of our microwave pressure vessels. see also: USP <233> Schwermetalle in Arzneimittel DIN EN 13805 & LMBG §35 - Schwermetalle in Lebensmittel DIN EN 13657 - Bestimmung von Schwermetallen in Abfall, Boden DIN EN 13346 - Phosphor in Klärschlamm DIN EN 1189 - Phsophor in Wasser DIN EN 1483 Quecksilber in WAsser DIN EN 14385- A Schwermetalle in Stäuben von Verbrennungsanlagen DIN EN ISO 15587\_1 - Bestimmung von Schwermetallen in Wasser DIN EN ISO 15587\_2 - Bestimmung von Schwermetallen in Wasser DIN EN 63321 Schwermetalle in Elektrogeräten (RoHS) |

|  |  |  |
| --- | --- | --- |
| 4005 | Date:  2023/05/04 18:10  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Berghof Products + Instruments GmbH  Org. country:  Germany | Answer to specific info request 6:  a. Sub-boiling system made entirely of fluoropolymers (PFA, PTFE or TFM). Mineral acids (HCl, HNO3, HF) are purified and/or recycled by subboiling system made of Fluoroplomers. The material must be chemically resistant up to max. 150°C and must not introduce any metallic impurities. We introduce <200 kg / year into EU market of Polytetrafluorethylen PTFE 9002-84-0 Polyfluoralokoxy PFA 26655-00-5 b. universal chemical resistance to concentrated mineral acids high T-range of application up to 150°C Purity of the materials - avoidance of contaminations with metals Hydrophobicity c. All universities and public research institutions in the STEM sector Contract and public testing laboratories, R&D in chemistry, pharma, food, automotive engineering, materials engineering, mining ... Quality control labs in environment, food, chemistry, pharma, automotive engineering, materials engineering, ... Competing companies: approx. 10 in EU e. No PFAS free alternatives available that cover all usecases of the current system. Quartz glass could be used for nitric and hydochloric acid. But Quartz is not resistant to hydrofluoric acid (HF). There is no alternative for applications with hydrofluoric acid (HF). Conclusion: There is no ready to use alternative avaílable and development of alternative solutions will take min. 3 years. It is unlikely that an alternative for usage of Hydroflouric acid will be found. Thus, even with derogations coving this applications it´ll be challenging to susbstitute Fluoropolymers in it for all usecases. Total estimated costs: 100.000 € g. A derogation is needed also to continue operation of the devices already in operation. Due to the special design of the pressure reactors and vessels, it is not possible to find alternatives that are compatible with them and could therefore be offered to existing customers as alternatives. A supply of spare parts and continued operation of the devices would therefore be impossible without an exemption. |
| Answer to specific info request 8:  Subboiling systems are mainly used in quality control and public or contract testing laboratories where high purity acids are required (materials testing, chemistry, pharma, food, environment, electronics ...). E.g. Analysis of Heavy metals in foodstuffs, waste/surface/drinking water, drugs or toys, monitoring of the RoHS directive in electrical appliances, etc. Consequences, if no derogations are granted: a. Sourcing high purity acids from chemical suppliers leads to signifcantly higher costs (price comparison for nitric acid: 299,- € vs. 47,- € per Liter; Suprapur vs. p.a. grade) and increases costs for above mentioned analysis. b. Without subboiling systems recycling of used acids isn´t possible any more. This applies to many instruments used in chemical laboratories. Most of them use Fluoropolymers too due to their universal chemical resistance and high operation temperature. Examples: AAS, ICP-AES, ICP-MS, GC, HPLC, titrators, liquid handling systems, centrifuges, and many others more. Therefore we´re sure this is of broad interest for the whole range of laboratory equipment. |

|  |  |  |
| --- | --- | --- |
| 4006 | Date:  2023/05/04 18:14  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Berghof Products + Instruments GmbH  Org. country:  Germany | Answer to specific info request 6:  a. O-Rings made of Flourorubber - For chemically resistant sealing of high pressure/temperature reactors up to 200bar & 300°C in chemical laboratories. O-rings must be chemically inert and in particular protect against attack by mineral acids, halogens or alkalis (HCl, HNO3, HF, Cl2, Br2, H2SO4, NaOH, NH3, .....). We introduce <100 kg / year into EU market Fluororubber FKM/FPM 64706-30-5 Perfluorinated Rubber FFKM 26425-79-6 b. universal chemical resistance to all kind of reagents optimal sealing properties in very special usecases like Viton 208 for Hydrogen-gas etc. high T-range of application up to 300°C hydrophobicity c. All universities and public research institutions in the STEM sector Contract and public testing laboratories, R&D in chemistry, pharma, food, automotive engineering, materials engineering, mining ... Quality control labs in environment, food, chemistry, pharma, automotive engineering, materials engineering, ... Competing companies: approx. 10 in EU e. No PFAS free alternatives available that cover all usecases of the current system. Other sealing materials do not offer this universal chemical range of application up to 300°C. Also sealing propertiers are unsurpasssed with Fluororubbers in various applications. For example, Viton 208 is the best exisiting seal for applications with Hydrogen Gas offering lowest leaking rates. New materials that may be suitable for special applications must be extensively tested with regard to their long-term chemical resistance. This is essential for safe operation of the products up to 200bar at 300°C. Different Silicon caoutchouc O-Rings may be applicable for certain usecases. Temperature is limited with Silicon caoutschouc to max. 150°C. Re-design to cool flanges is required therefore. Application-specific solutions have to be developed and introduced into the markets. Users therefore need several solutions and more operating know-how. Conclusion: There is no ready to use alternative avaílable and development of alternative solutions will take min. 8 years. WWe do not have the ressources to develop new materials but depend on suppliers in this respect. So at first, potential alternatives have to be found, extensivley tested with all kind of chemical reagents to assure. Thus, even with derogations coving our products and applications it´ll be challenging to susbstitute Fluoropolymers in our products for all usecases. Total estimated costs: 500.000 € g. A derogation is needed also to continue operation of the devices already in operation. Due to the special design of the pressure reactors and vessels, it is not possible to find alternatives that are compatible with them and could therefore be offered to existing customers as alternatives. A supply of spare parts and continued operation of the devices would therefore be impossible without an exemption. |
| Answer to specific info request 8:  High-pressure reactors are mainly used in research and development (universities, chemistry, pharma, automotive, materials technology, food) but also in quality control or public and contract testing laboratories (materials testing, chemistry, pharma, food, environment, electronics ...). Examples of applications are investigations of material embrittlement under hydrogen overpressure, ageing of sealing materials, the production of zeolites, nanoparticles, catalysis research, etc. Consequences, if no derogations are granted: a. Lower performing materials will hinder technological progress in these and other high tech areas. b. Impropper corrosion protection of pressure-bearing parts leads to a potential safety issue with the operation of our high-pressure reactors c. Additional application development will result in higher product prices. This applies to many instruments used in chemical laboratories. Most of them use Fluoropolymers too due to their universal chemical resistance and high operation temperature. Examples: AAS, ICP-AES, ICP-MS, GC, HPLC, titrators, liquid handling systems, centrifuges, and many others more. Therefore we´re sure this is of broad interest for the whole range of laboratory equipment. |

|  |  |  |
| --- | --- | --- |
| 4007 | Date:  2023/05/04 18:17  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Berghof Products + Instruments GmbH  Org. country:  Germany | Answer to specific info request 6:  a. High pressure reactors and pressure vessles with corrosion protection coating or lining made of PFA or PTFE: To protect metal parts against corrosion in chemical laboratories, especially against mineral acids or alkalis. For the safe operation of high-pressure reactors, pressure-bearing parts, temperature or pressure sensors are protected against chemical attack.This must be chemically inert and in particular protect against attack by mineral acids, halogens or alkalis (HCl, HNO3, HF, Cl2, Br2, H2SO4, NaOH, NH3, .....). We introduce <750 kg / year into EU markett Polytetrafluorethylen PTFE 9002-84-0 Polyfluoralokoxy PFA 26655-00-5 Polyfluor-ethylene-propylene FEP 25067-11-2 b. universal chemical resistance to all kind of reagents high T-range of application up to 300°C hydrophobicity c. All universities and public research institutions in the STEM sector Contract and public testing laboratories, R&D in chemistry, pharma, food, automotive engineering, materials engineering, mining ... Quality control labs in environment, food, chemistry, pharma, automotive engineering, materials engineering, ... Competing companies: approx. 10 in EU e. No PFAS free alternatives available that cover all usecases of the current system. Glass or ceramic coating may be applicable for certain usecases but don´t provide universal chemical resistance like Fluoroploymers. Long-term adherence of these coatings on base alloys of the reactors must be assured and has to be evaluated. Weakening pressure-bearing parts due to chemical attack with high pressure reactors increase risks of operators. Conclusion: There is no ready to use alternative avaílable and development of alternative solutions will take min. 8 years. We do not have the ressources to perform basic materialscience on coating materials. So at first, potential alternatives have to be found, extensivley tested with all kind of chemical reagents to assure. Thus, even with derogations coving our products and applications it´ll be challenging to susbstitute Fluoropolymers in our products for all usecases. Total estimated costs: 1 Mio. € g. A derogation is needed also to continue operation of the devices already in operation. Due to the special design of the pressure reactors and vessels, it is not possible to find alternatives that are compatible with them and could therefore be offered to existing customers as alternatives. A supply of spare parts and continued operation of the devices would therefore be impossible without an exemption. |
| Answer to specific info request 8:  High-pressure reactors are mainly used in research and development (universities, chemistry, pharma, automotive, materials technology, food) but also in quality control or public and contract testing laboratories (materials testing, chemistry, pharma, food, environment, electronics ...). Examples of applications are investigations of material embrittlement under hydrogen overpressure, ageing of sealing materials, the production of zeolites, nanoparticles, catalysis research, etc. Consequences, if no derogations are granted: a. Lower performing materials will hinder technological progress in these and other high tech areas. b. Impropper corrosion protection of pressure-bearing parts leads to a potential safety issue with the operation of our high-pressure reactors c. Additional application development will result in higher product prices. This applies to many instruments used in chemical laboratories. Most of them use Fluoropolymers too due to their universal chemical resistance and high operation temperature. Examples: AAS, ICP-AES, ICP-MS, GC, HPLC, titrators, liquid handling systems, centrifuges, and many others more. Therefore we´re sure this is of broad interest for the whole range of laboratory equipment. |

|  |  |  |
| --- | --- | --- |
| 4008 | Date:  2023/05/04 18:23  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Geberit International AG  Org. country:  Switzerland  Attachment:    <redacted>  Privacy statement:  contains non-public/sensitive technical and business information and trade secrets | General Comments:  Please see non-confidential attachment for our general comment. |
| Answer to specific info request 1:  Our comments apply to the sanitary industry sector, a sector not yet identified in Annex XV restriction report. See Comments on Question 6. |
| Answer to specific info request 6:  All uses in the sanitary industry are missing. In the non-confidential attachment, we provide detailed information on three exemplary use cases of PFASs in sanitary industry. They all have in common, that they are bound to strict normative requirements, approvals, and certifications. A change to a PFAS free alternative is not feasible within the 18 month transition period nor the 5-year derogation period. Therefore, we request a 12-year derogation period for application in the sanitary industry. |

|  |  |  |
| --- | --- | --- |
| 4009 | Date:  2023/05/04 23:14  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SHPP B.V. and SABIC Innovative Plastics B.V.  Org. country:  Netherlands  Attachment:    <redacted> | Answer to specific info request 6:  See attachments in Sections IV and V below. |