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

**Specific information requests:**

1. **Sectors and (sub-)uses**: Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.
2. **Emissions in the end-of-life phase**: The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:
3. Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.
4. If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.
5. **Emissions in the end-of-life phase**: With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.
6. **Impacts on the recycling industry**: To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:
7. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).
8. The measures that recyclers would need to take to achieve the proposed concentration limits.
9. The costs associated with these measures.
10. **Proposed derogations – Tonnage and emissions**: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.
11. **Missing uses – Analysis of alternatives and socio-economic analysis**: Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:
12. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
13. The key functionalities provided by PFAS for the relevant use.
14. The number of companies in the sector estimated to be affected by the restriction.
15. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.
16. For cases in which **alternatives are not yet available**, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.
17. For cases in which **substitution is technically and economically feasible** but more time is required to substitute:
    1. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);
    2. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
    3. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);
    4. information on the benefits for alternative providers.
18. For cases in which **substitution is not technically or economically feasible**, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.
19. **Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis**: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

1. **Other identified uses – Analysis of alternatives and socio-economic analysis**: Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.

For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.

More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

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

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| 8109 | Date:  2023/09/21 02:38  Content:  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Canada  Company name confidential:  Yes  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Substance of PFAS: Diazirine-based chemical crosslinking monomers containing two fully fluorinated methyl (CF3-) carbon atoms per molecule (without any H/Cl/Br/I attached to them). Our products: BondLynx BLD-201 (CAS 2816776-70-0) and related bis-diazirine molecules. Product applications: Expected to be used in a wide range of applications, including the manufacture of semiconductor devices and displays. |
| Answer to specific info request 5:  PFAS production: Approximately 2 tons/year by 2030 |
| Answer to specific info request 6:  a) Products using the substances are expected to be used in a wide range of applications, including semiconductor devices and displays. It is a critical additive to the base polymer in photosensitive adhesives. Estimated annual production will ramp up from a few pounds/year to approximately 2 tons/year by 2030. b) The substance has the following simultaneous performance requirements: It must be solvent-soluble, developer-soluble, transparent, and have appropriate dielectric properties. It is a critical additive to (and covalently crosslinks with) the base polymer in photosensitive adhesives. The required performance is essential for the manufacture of high-performance semiconductor devices and displays, and is an extremely important component for the semiconductor and display industries. c) It is estimated that companies in the field such as manufacturers of semiconductor devices and displays will be greatly affected by the inability to use the substances. d) There are currently no potential substitutes on the market. e) Development of the bis-diazirine chemical crosslinkers has taken more than four years, and R&D is underway on the development of non-fluorine based alternatives. However, at this time, no technically or economically replaceable substance has yet been developed, making the introduction of replacement substances particularly challenging. f) At the current time, there is no technologically and economically feasible alternative. g) The socioeconomic impact on companies, consumers, and other stakeholders is expected to make it difficult for electronics products such as smartwatches and smartphones to cope with the miniaturization of advanced functions. Based on the above, PFAS regulations should exempt these substances from this proposed restriction since there are no appropriate substitutes. |
| Answer to specific info request 10:  See synthesis and NMR spectra for Compound 9 in the attached Non-confidential Document. |

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| 8110 | Date:  2023/09/21 03:37  Type:  Individual  Country:  United States of America  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 6:  lithium-ion rechargeable battery electrode binders currently using PVDF polymers. Other none PFAS containing polymers may partially or completely replace PVDF binder for lithium-ion rechargeable battery applications. The replacement binder also enables green recycling of the lithium-ion batteries with no PFAS emission. Please refer to the peer-reviewed scientific publication on the alternative electrode binders: Liu, Z. M.; He, X.; Fang, C.; Camacho-Forero, L. E.; Zhao, Y. Z.; Fu, Y. B.; Feng, J.; Kostecki, R.; Balbuena, P. B.; Zhang, J. H.; Lei, J. X.; Liu, G., Reversible Crosslinked Polymer Binder for Recyclable Lithium Sulfur Batteries with High Performance. Advanced Functional Materials 2020, 30 (36), 9. Please also refer to the links for more information on this new technology: https://www.forbes.com/sites/alanohnsman/2023/02/01/a-new-glue-could-make-lithium-ion-battery-recycling-cheaper---and-less-toxic/?sh=7f6ca4fd5da3 https://newscenter.lbl.gov/2023/02/01/an-easy-new-way-to-recycle-batteries-is-here/#:~:text=A%20battery%20made%20with%20Quick,the%20water%20and%20air%2Ddried. |

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| 8111 | Date:  2023/09/21 04:56  Content:  Information on alternatives  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Ninomiya Electric Wire Co., Ltd.  Org. country:  Japan  Attachment:    <redacted>  Privacy statement:  To include company economic information | General Comments:  Ninomiya Electric Wire Co., Ltd. supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV. Ninomiya Electric Wire Co., Ltd. opposes the uniform limitation of fluoropolymer as PFAS. If fluoropolymer is limited as it is, there is no alternative material that can achieve heat resistance, chemical resistance, and high-performance electrical properties. Silicon rubber and PVC listed as alternative candidates are not performing well. A case study of use of Ninomiya Electric Wire Co., Ltd. that could not be substituted is attached to IV. As per attached in Section IV, the lack of fluoropolymer wires will face a serious crisis in the manufacture of semiconductor manufacturing equipment. Semiconductors cannot be manufactured without semiconductor manufacturing equipment. In other words, if fluoropolymer is restricted and cannot be used, it means semiconductors cannot be manufactured. We fell into a crisis of semiconductor shortage due to the COVID-19. If fluoropolymer is restricted, in EU area, major confusion will be caused again like that. Fluoropolymer is also used in a variety of fields other than the wire insulated by fluoropolymer we use. Limited fluoropolymer, that has a variety of negative consequences for BEV and hydrogen-utilizing The European Green Deal Investment Plan. |

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| 8112 | Date:  2023/09/21 05:11  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  A wide variety of PFAS-applied products on the market are closely related to the European Green Deal. We believe that this proposal to regulate PFAS will have significant implications for the European Green Deal, which is targeted to be achieved by 2050. In REACH, persistence is subject to risk assessment only when combined with bioaccumulation and in some cases with toxicity. However, this restriction proposal is based on persistence alone, which is not considered a hazard endpoint, as if all PFASs are hazardous. In addition, while exposure assessments should be made for each use by creating exposure scenarios, all PFASs are grouped together, so the assessment for each use is insufficient and does not indicate the existence of unacceptable risks as required by Article 68. Therefore, we believe that this proposal does not meet the requirements for a restriction proposal as required by REACH, and it is not appropriate to discuss a restriction. In addition to the exclusion of fully degradable PFAS, we think risk of PFAS with potential to degrade (soil remediation potential) would not be “unacceptable risk” and the risk of each substance should be quantitatively assessed and discussed. The current PFAS regulation will have a tremendous impact on the chemical industry, which provides materials for a wide variety of applications and products, and will affect not only the chemical industry but also the global supply chain. Since PFAS-applied products cover a wide range, there is a high possibility of a situation that cannot be handled by testing laboratories that carry out tests to prove that PFAS is not contained in products. In addition, for some PFAS, even analysis methods have not been established. Furthermore, these tests require a great deal of time and new economic burdens, and many businesses are forced to give up their businesses, which may result in a large number of unemployed people. |
| Answer to specific info request 1:  Foam blowing agents |
| Answer to specific info request 7:  Fluorinated gases are highly safe substances in terms of toxicity and flammability, and are used in many applications due to their efficiency and cost. In particular, on-site foam polyurethane spray insulation exhibits excellent insulation performance, and fluorinated gas is indispensable for preventing fires during spraying work. Refference 1 shows that about 2% trifluoroacetic acid (TFA) is produced by the reaction of HFO-1233zd(E) with OH radicals in atmosphere. Reference 2 also reports that the evidence is clear and irrefutable that TFA occurs naturally in large quantities in the environment.Furthermore, according to references3 and 4, TFA which are of concern in the proposed regulations, actually pose a low risk of toxicity to living organisms and humans, even in the reports of the German and Norwegian environmental agencies that submitted this proposed regulation. In addition, according to Reference 5, HFO-1233zd(E) is negative in the OECD TG471 Ames test and negative in the OECD TG473 chromosome aberration test, so it is expected to have no mutagenicity. The LC50 (rat) in the inhalation test was 120,000 ppm, and the NOAEC (No Observed Adverse Effect Concentration) in the OECD TG413 90-day repeated inhalation test was 4,000 ppm. The working environment exposure limit (WEEL) of 800 ppm (8 hours, TWA) was determined, and toxicity to humans is expected to be low. Further, Reference 6 reported that “UV-driven photodegradation of some of the compounds controlled by the Montreal Protocol (e.g., hydrofluorocarbons (HFCs))produce contaminants such as trifluoroacetic acid (TFA), but concentrations of these breakdown products in the environment are currently deemed too low to be a concern for human health or the environment." Therefore, we request that fluorinated gas including HFO-1233zd(E) for this application be exempted from the application or given as a special exemption without a time limit. Ref.1：Atmospheric Environment vol179, 2018, P250-259 https://doi.org/10.1016/j.atmosenv.2018.02.018 Ref.2：EFCTC summary publication Naturally Occurring TFA. https://www.fluorocarbons.org/wp-content/uploads/2020/08/EFCTC-TheEvidenceThatTFAoccursNaturally\_A4.pdf Ref.3：German Environment Agency, Reducing chemical input into water bodies trifluoroacetate (TFA) as a persistent and mobile substance from many sources, 2021 Ref.4：Norwegian Environment Agency, Study on environmental and health effects of HFO refrigerants, 2017 Ref.5：Workplace Environmental Exposure Level (HCFO-1233zd(E)) https://tera.org/OARS/1233zdE%20HCFO%20OARS%20WEEL%20Public%20Comment.pdf Ref.6：Pages 8-9, Summary Update 2021 for Policymakers, UNEP Environmental Effects Assessment Panel Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate According to Volume 1: Progress Report published in May 2023 by the Technology and Economic Assessment Panel (TEAP), the technical and economic advisory body for the parties to the Montreal Protocol, points out " If mainstream uses of F-gases are limited in Europe, there could be broader implications for investment in HFOs and HCFOs going forward. " In addition, according to the "2022 Assessment Report" released by the FTOC (Flexible and Rigid Foams Technical Options Committee) reported that " Some European governments are consulting on the development of regulations related to per- and poly-fluoroalkyl substances (PFAS), the definition of which may or may not include Montreal Protocol controlled substances and their substitutes. This is creating uncertainty for industry regarding long-term availability of some alternatives. Some companies and other stakeholders have reported that they are delaying decisions regarding selection of alternatives with concerns about how some or all those fluorinated alternatives might be limited as a result of future regulations.” Ref.1：TEAP Progress Report 2023 https://ozone.unep.org/system/files/documents/TEAP-May2023%20Progress%20Report.pdf Ref.2：FTOC 2022 Assessment Report https://ozone.unep.org/system/files/documents/FTOC-Assessment-Report-2022.pdf |

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| 8113 | Date:  2023/09/21 05:32  Content:  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 7:  We use various fluoropolymers such as Ethylene tetrafluoro ethylene (ETFE), Fluorinated ethylene propylene (FEP), Perfluoroalkoxy alkane (PFA) and Polytetrafluoroetylene (PTFE) as insulation and buffer materials for our cables. Fluoropolymers are the only materials that simultaneously possess the excellent features listed in 1) to 5) above. 1) Wide operating temperature range Fluoropolymers are the only materials that can operate in high-temperature environments of 250°C or higher. It is the only material that can maintain elasticity in extremely cold environments of -100°C or lower. 2) Higher resistance to weather, chemicals, oil, and flame than other materials Material with extremely low dielectric breakdown under exposure to ultraviolet rays and ionizing radiation. Extremely little mechanical deterioration due to corrosion from corrosive gases, acids/alkalis, organic solvents, and various types of oil. Corrosive gases, acids, alkalis, organic solvents, various oils, and other corrosives. High oxygen index of 95% or higher, making it a material that is difficult to burn. 3) Combines lubricity, wear resistance, tensile strength, bending modulus and elongation not found in other materials. Coating materials that combine high tensile strength with high flexural modulus and elongation include alternative materials (silicone materials, polyether ether ketone (PEEK), mica, EPDM, polyvinyl chloride, polyethylene, ceramic based and one confidential polymer). There are no alternative coating materials other than fluoropolymers, including alternative materials (Silicone materials, Polyether ether ketone (PEEK), mica, EPDM, Polyvinyl chloride, Polyethylene, ceramic based and one confidential polymer). There are no alternative materials (silicone materials, Polyether ether ketone (PEEK), mica, EPDM, Polyvinyl chloride, Polyethylene, ceramic based and one confidential polymer). The material has water repellency, lubricity, abrasion resistance, and non-adhesiveness at the same time. Fluoropolymers that combine these characteristics are necessary materials for long-life movable wires. 4) Extremely high voltage resistance and the lowest dielectric constant and dissipation factor among polymers Lowest dielectric constant and dielectric loss tangent of any alternative material (silicone materials, polyether ether ketone (PEEK), mica, EPDM, polyvinyl chloride, polyethylene, ceramic based and one confidential polymer) The volume resistivity (>1018Ω-cm) is higher than that of alternative materials (silicone materials, polyether ether ketone (PEEK), mica, EPDM, polyvinyl chloride, polyethylene, ceramic based and one confidential polymer) Lowest dielectric constant (2.1) and dissipation factor (2×10-4) among all polymers. It is an ideal material for high-speed transmission. 5) Thin-wall Formability Unmatched by Other Materials High elongation allows for excellent thin-wall formability. About cables for moving parts Cables for moving parts are used in a variety of equipment because they can supply power to the end of the equipment as sensor cables and motor power cables without breaking while the cable is moving. They are mainly used in industrial robots (e.g., articulated robots with multiple axes, scalar robots, and robots that move on XY stages). Industrial robots are required to be automated and highly precise in manufacturing production lines and are responsible for labor production shortages. Fluoropolymers used for cables for moving parts, as explained above, have a high volume resistivity and can reduce the insulation thickness, making it possible to make thinner cables while maintaining the insulation performance than cables using other insulation materials. Robots have been miniaturized in recent years, and cables are required to be moving parts with narrow wiring. Going forward, cables will continue to need to be made thinner. The only resin that can meet this requirement is fluoroplastic. If the cables are too thick, they cannot be routed inside the robot and the robot housing itself will become huge, and the motors to move them will also become larger and use more electricity. As a result, CO2 emissions will increase, worsening the global environment. Since ETFE, FEP, and PFA have high mechanical properties such as tensile strength, elongation, and hardness, the resin will not crack or break due to movement, and wires coated with ETFE, FEP, or PFA can be used as wires for moving parts. If wires made of other insulation materials are made to move, the insulation will crack and lose its insulating properties, making them unusable as wires for moving parts. In particular, FEP has a low dielectric constant and is a material that combines telecommunication characteristics such as attenuation and leakage with a small diameter. In terms of durability under movement, fluoropolymer-insulated conductors are 1.9 times more durable than PVC-insulated conductors and 1.2 times more durable than cross-linked polyethylene conductors. (See Appendix for test conditions and results.) PTFE is also an essential material for cables used in moving parts. PTFE (in tape form), which has a low coefficient of friction, is applied to the inside of the wire. By applying PTFE (in the form of tape) as a buffer between the wire core and the shield, it is possible to prevent the shaving of insulation by the metal shield that occurs when the cable is moved. PTFE also has a high elongation, so it is a material with no alternative that can withstand the violent movements caused by repeated movement and maintain cushioning protection without cracking. Our Impact Even if we were to switch to an alternative material to PFAS, we would need to replace five extruders, and we would not be able to bear the cost of the equipment. Even if the company could bear the cost, it would take more than seven years to replace the equipment. Our cables for moving parts are designed and proposed in accordance with the operating conditions of each machine and robot, and are used not only in Japan but also throughout the world. We are a manufacturer that supplies approximately 10,000 types of cables for moving parts to the world, More than 90% of its products (cables for moving parts) are made of fluoroplastic. Fluoropolymers are indispensable to our company, and maintaining the same level of performance and sales with non-fluoropolymers is technically and economically unfeasible, and we can expect to be unable to maintain our 180 employees. In addition, it is easy to believe that it would put the entire society at risk of slowing down the pace of development of manufacturing. Based on the above, we advocate the continued use of ETFE, FEP, PFA, and PTFE. |

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| 8114 | Date:  2023/09/21 06:09  Content:  Scope or restriction option analysis  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  Many lubricants which include such PFASs as perfluoropolyethers (PFPEs), polytetrafluoroethylene (PTFE), and fluorinated additives have been applied to a lot of machinery and equipment for more than some decades to realize various requirements from industries and markets: safe functioning, safety of equipment, withstanding harsh conditions, a necessary service life, etc. We think that this all-inclusive restriction proposal against PFASs is not appropriate to the lubricants and the industries as lubricant users. Our understanding about the lubricants under the restriction proposal is as follows: no alternatives to PFASs exist at present, there is a possibility that the alternatives won’t appear during and after the transition and derogation period, and the proposal doesn’t include any clauses of exemptions about the lubricants. If the PFAS restriction without right care comes into force, the restriction probably disturbs and deteriorates various activities regarding the industries and markets. We also think that it is very difficult for PFAS-free lubricants to meet the various requirements from the industries and markets because non-PFAS materials don’t have the same properties as the PFAS substances. Therefore, we submit our comments, technical views, and others with the PFAS-containing lubricants, especially greases. Japan Grease Institute already provided several comments for the annex XV restriction report. This will support and supplement theirs. We hope that all comments and data will be helpful to you. |
| Answer to specific info request 1:  We apply our comments to “Lubricants (Annex E.2.14.), Sector as a whole” in the table 9 of ANNEX XV RESTRICTION REPORT. |
| Answer to specific info request 5:  We show several data in our confidential attachment. Please refer to the confidential attachment. |
| Answer to specific info request 6:  a) We show some data in the confidential attachment. Please refer to the confidential attachment. b) We show key functionalities regarding PFASs and some relevant information in the confidential attachment. Please refer to the confidential attachment. g) This comment in this paragraph supplements the preceding paragraph b). Grease techniques with the PFAS materials are one of the most sophisticated grease technologies at present. Since the techniques result from the excellent diverse and distinctive properties of PFASs, the non-PFAS substances without the same chemical and physical characteristics as PFASs can’t realize the techniques. In this above field, PFASs generally have notable characteristics to the industries and markets in comparison with the non-PFAS materials. Therefore, except for cases applying the PFAS-containing greases with properties over required specifications to the machinery and equipment at present, we guess that the lack of the said techniques significantly impacts the appropriate motions and functions of the machinery and equipment using the above techniques and the various activities in the industries and markets. Please refer to the confidential attachment. |
| Answer to specific info request 7:  We agree about Japan Grease Institute’s comment to this topic. The PFAS-applied lubricants are like one of the symbols of “the end point of lubricant technology”. We can’t change PFASs to the PFAS-free materials about the lubricants because the technology using PFASs is currently very essential to the machinery and equipment and the non-PFAS alternatives don’t exist. Please refer to the confidential attachment. The diverse and peculiar properties of the lubricants gained by PFASs can't be achieved by the non-PFAS substances because the non-PFAS substances don't have the same properties as PFASs. Therefore, just before the end of "a transition period of 18 months and a 12-year derogation" for the lubricants in the table 9 of ANNEX XV RESTRICTION REPORT, p.138, in the event of no existence of any applicable PFAS-free lubricants and feasible mechanical countermeasures realizing non-PFAS lubrication and when the industries and markets have to avoid any loss, damage, and unsafe conditions resulting from the non-use of PFASs, the current restriction proposal of PFASs needs the following relief measures: 1) the derogation period can be renewed for successive derogation periods and/or 2) manufacturers, importers, and downstream users can manufacture, place on the market, and use the PFAS substances through an approval process after the transition and derogation period. |
| Answer to specific info request 8:  We agree about Japan Grease Institute’s comment to this topic. The industries and markets need to treat all applications under no alternative materials at present within the rule of the transition period of 18 months and the 12-year derogation for the lubricants in the table 9 of ANNEX XV RESTRICTION REPORT at least in order to maintain the various activities and avoid any loss, damage, and unsafe conditions resulting from the non-use of the PFAS-containing lubricants. The PFAS-containing greases are not chosen by only whether harsh or non-harsh conditions. Being expensive, PFASs are generally applied to the greases in special cases as far as we know. |

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| 8115 | Date:  2023/09/21 07:44  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SYNZTEC　CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test date | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors |
| Answer to specific info request 7:  Section V Attachments Reference |

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| 8116 | Date:  2023/09/21 07:52  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SYNZTEC　CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors |
| Answer to specific info request 7:  Section V Attachments Reference |

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| 8117 | Date:  2023/09/21 07:53  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SYNZTEC　CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors |
| Answer to specific info request 7:  Section V Attachments Reference |

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| 8118 | Date:  2023/09/21 07:58  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SYNZTEC　CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors |
| Answer to specific info request 7:  Section V Attachments Reference |

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| 8119 | Date:  2023/09/21 08:04  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SYNZTEC　CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors |
| Answer to specific info request 7:  Section V Attachments Reference |

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| 8120 | Date:  2023/09/21 08:07  Content:  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  International NGO  Org. name:  Global Initiative for Chronic Obstructive Lung Disease (GOLD)  Org. country:  United States of America  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Medical devices (Annex E.2.9.); Metered Dose Inhalers |
| Answer to specific info request 7:  Information provided on substitution potential and need for specific time-limited derogations. |

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| 8121 | Date:  2023/09/21 08:09  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SYNZTEC　CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors |
| Answer to specific info request 7:  Section V Attachments Reference |

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| 8122 | Date:  2023/09/21 08:12  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Inner Mongolia 3F Wanhao Fluorochemical Co., Ltd.  Org. country:  China | General Comments:  On behalf of Inner Mongolia 3F Wanhao Fluorochemical Co., Ltd., we would like to extend greetings to the 5 countries proposing the ECHA and PFAS control draft. We have been making unremitting efforts to comply with domestic and international regulations, and continue to conduct strict self-review of products exported to the EU for compliance. We have long supported ambitious attempts by the EU to reduce the risks caused by toxic and hazardous substances and take practical measures in good faith to meet the requirements of EU chemicals regulations, including REACH. Inner Mongolia 3F Wanhao Fluorochemical Co., Ltd. is a main polyvinylidene fluoride resin and fluorine rubber products enterprise. For polyvinylidene fluoride resin coatings, we use perfluoropolyether to achieve stable polymerization reaction, excellent product performance, with strong chemical corrosion resistance, strong weather resistance and other unique requirements. Since there is no viable alternative for this application, and even if the alternative is certified, complete elimination will take longer due to previous pipe residue, we request an unlimited time extension for this use application. In this application, PFASs has the properties of repelling water and oil, heat resistance, chemical substances and non-absorption of light, and has been widely used in water repellents, surface treatment agents, emulsifiers, fire extinguishers, coatings, etc., as well as a wide range of industrial applications such as semiconductors, automotive and batteries. Many of these applications and uses are considered "essential applications." Specifically, the viscosity of PVDF has a great impact on the production, storage and construction of coatings, as well as the cost of coatings. Viscidity exorbitance will have a bad impact on production and construction, especially in the case of high leveling requirements in the construction, such as coil coating will be difficult to meet the requirements, it is too low viscosity to achieve the same factory viscosity index means the increase in solid content and the increase in cost. At present, the alternatives that exist in the market and the draft cannot be completely replaced. Regarding this bill, we also have the following comments: 1.Summary, Introduction, page 1 of the text, two paragraphs: Introduction This Annex XV report addresses the risks to the environment and human health of the use of per- and polyfluoroalkyl substances (PFASs) and provides an assessment of the effectiveness, practicability, monitorability and socio-economic impacts of two restriction options (ROs) under REACH as the most suitable risk management option (RMO) to address the identified risks. PFASs are a group of thousands of mainly man-made substances that are used in numerous applications in the EU. These applications comprise uses in textiles, (food) packaging, lubricants, refrigerants, electronics, construction and many more. The substances are used as substances on their own (either non-polymeric or polymeric) and as constituents in mixtures and (complex) articles for consumer, professional, and industrial uses. The annex XV report deals with risks to the environment and human health of the use of perfluorinated and polyfluoroalkyl substances (PFASs). and provides an assessment of the effectiveness, practicability, monitorability and socio-economic impacts of two restriction options (ROs) under REACH as the most suitable risk management option (RMO) to address the identified risks， and provides an assessment of the effectiveness, practicability, monitorability and socio-economic impacts of two restriction options (ROs) under REACH as the most suitable risk management option (RMO) to address the identified risks. PFASs are a group of thousands of mainly man-made substances that are used in numerous applications in the EU. These applications comprise uses in textiles, (food) packaging, lubricants, refrigerants, electronics, construction and many more. The substances are used as substances on their own (either non-polymeric or polymeric) and as constituents in mixtures and (complex) articles for consumer, professional, and industrial uses. Opinion: This report mentions the risk, but what does risk specifically mean? What are the environmental and human health risks? There is no exact number of PFASs in the proposal, only thousands, is that 1,000, 2,000 or 10,000? So each of these many substances carries the same risk? Can it be equated? What does "composite" products mean? Products or composite products? For our PVDF, the whole process of suspension polymerization does not contain fluorine additives, and the final PVDF product is a product or a composite product? Without PFAS sources, how can PVDF be placed on the prohibited list? 2. Scope text page 2, paragraph 1, Restrictions text page 4, column 2: Scope The chemical scope of the restriction proposal is defined as: Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it). There are however a few exceptions (see para below). Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) in a concentration of or above: i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification) iii. 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. Opinion: The scope of chemicals in this restriction proposal is defined as follows: any substance containing at least one perfluoromethyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it). This definition is consistent with the OECD's PFASs definition, which was published in 2021.The definition has been carefully reviewed by the international scientific community and is already widely accepted. This definition covers more than 10,000 PFASs, including a small number of fully degradable PFAS subgroups. At present, there are only a few hundred known detection methods, which is far from 10,000. Since there are so many definitions, and we cannot know all the detection methods, how did the 10,000 methods come up? And the restriction in the second column of Restriction Option 2: Any PFAS determined by targeted PFAS analysis (polymerized PFASs) is 25 ppb. 250 ppb is the sum of PFASs, as the sum of the target PFAS analysis, it can be selected with the previous precursor degradation (polymer PFASs excluded from quantification). PFASs 50ppm (including polymer PFASs). If the total fluorine content exceeds 50 mg F/kg, manufacturers, importers and downstream users should provide a fluorine certificate as a PFASs and non-PFASs content measurement to law enforcement authorities upon request. Even the detection methods are not complete, how to ensure that the PFASs sum of more than 10,000 substances can be measured does not exceed 250ppb; In addition, it is a fluoropolymer, Can the total fluorine content not exceed 50 mg F/kg? Is it a contradiction? 3、Article and mixture manufacturing emissions，Text, page 40, paragraph 3 Application of fluoropolymer coatings, an important PFAS application method in many sectors, could lead to emissions from product manufacturing sites (Langberg et al., 2021). Although processes are likely closed, some PFAS (micropowder) emissions might occur that are not accounted for in ERCs. During the call for evidence and the 2nd stakeholder consultation, the amount of information received on emissions related to article manufacturing was very limited. Based on US permit information, in PFAS paste extrusion lines, printing lines, melt extrusion lines and fuse lines there is potential to generate toxic thermal PFAS decomposition products. Emissions are not quantifiable as they are highly variable due to variations in e.g. oven temperature and line speed. But emissions are likely. Therefore, the emissions calculated for product manufacturing using ERCs might be an underestimation. Opinion: This paragraph proposes that fluoropolymer coatings are an important application method for PFAS in many fields, which may lead to emissions at the product manufacturing site(Langberg et al.，2021). Although the process may be closed, some emissions of PFAS (micro-powders) may occur in the erc with very limited emission information received during the call for evidence and the second stakeholder consultation in connection with the manufacture of the article. The bill raised that fluoropolymer coatings could probably lead to emissions at product manufacturing sites. That's the word "probably". At present, there is no exact data to prove that fluoropolymer coatings will definitely cause PFAS emission and affect the environment, so we believe that fluoropolymer coatings are not completely PFAS emission, therefore, it is not possible to generically ban all fluoropolymer coatings. 4. Summary, Concern, page 1, first paragraph: Concern The main concern for all PFASs and/or their degradation products that are in the scope of this restriction proposal is the very high persistence, exceeding the criterion for very persistent (vP) according to Annex XIII of the REACH Regulation by far. PFASs and their degradation products may persist in the environment longer than any other man-made chemical. Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. PFASs enter the environment via emissions during manufacture, the use phase, and the waste stage. Opinion: The main concern for all PFASs and/or their degradation products within the scope of this proposed restriction is the very high persistence. Significantly exceeding the very persistent standards set out in Annex XIII of REACH (vP, very persistent). PFASs and their degradation products may persist in the environment longer than any other human-made chemical. Further supporting concerns are their bioaccumulation, mobility, long range transport potential, and accumulation in plants), global warming potential, (eco)toxicological effects. PFASs enter the environment via emissions during manufacture, the use phase, and the waste stage. So what is the relationship between persistence and risk? Is persistence necessarily a risk? Is there reliable data to support it? Is fear a good enough reason for restriction? Do these substances all have these negative characteristics? Is the durability of all substances the same? Persistence is not sufficient to divide PFAS and assess human health risks. For example, perfluorinated propylene is defined as a PFAS substance, it is durable regard to the concerns mentioned above. However, according to our contact, when sampling perfluoropropylene for analysis, accidentally inserting a needle into the skin, as long as the blood is squeezed out, it has no impact on the body, and it has not been found to be persistent, which has a huge impact on our health. |

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| 8123 | Date:  2023/09/21 08:26  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment: | General Comments:  see attachment |
| Answer to specific info request 1:  see attachment |
| Answer to specific info request 2:  see attachment |
| Answer to specific info request 3:  see attachment |
| Answer to specific info request 4:  see attachment |
| Answer to specific info request 5:  see attachment |
| Answer to specific info request 6:  see attachment |
| Answer to specific info request 7:  see attanchment |
| Answer to specific info request 8:  see attachment |

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| 8124 | Date:  2023/09/21 08:46  Content:  Scope or restriction option analysis  Environmental emissions  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SAKAGAMI SEISAKUSHO LTD.  Org. country:  Japan  Attachment:  <redacted> | General Comments:  We manufacture sealing parts for actuators that mainly use fluids, mainly hydraulic and pneumatic, and sell REACH-compliant products in the EU, we sell REACH compliant products within the EU. The applications range from public transportation such as automobiles, construction machinery, and railroads to various industrial components such as agricultural machinery, food machinery, and semiconductors, as well as control equipment for power plants, including nuclear power plants. These industrial machines are used in the manufacture of all the essentials needed to support daily life in the modern world. Our sealing components are the parts that support the foundation of these industrial machines. Therefore, the impact on various social activities in general can be judged to be enormous. 　 It is therefore proposed that a permanent derogation or a permanent exemption be granted for this use case, referred to as ‘industrial automation components and equipment.' |
| Answer to specific info request 1:  We manufacture and sells sealing parts for actuators that use mainly fluids, mainly hydraulic and pneumatic. Its applications range from public transportation such as automobiles, construction machinery, and railroads to various industrial parts such as agricultural machinery, food machinery, and semiconductors, as well as production plants such as steel mills and control equipment for power plants including nuclear power plants. Therefore, the impact on various social activities in general is enormous and difficult to deal with. In view of this, we request that permanent exemptions or exemptions be granted for all components. |
| Answer to specific info request 2:  We have maintained ISO14001 certification since 2003 and are committed to fulfilling our social responsibility to the environment. These efforts include compliance with the revised RoHS Directive, and the "Revised RoHS Directive Compliance Regulations" have been issued and incorporated into the management system. 　All PTFE and fluorine rubber emitted during our manufacturing processes are disposed of appropriately in accordance with legal regulations and in a manner that is currently considered to have the least impact on the environment. In addition, since items shipped as products are used by organizations, not individuals, and since items such as automobiles are subject to disposal based on laws and regulations, we believe that disposal in accordance with laws and regulations is being properly implemented. |
| Answer to specific info request 5:  We supply PTFE products as seals for power steering and gas dampers for automobiles. 　Chips emitted from cutting operations are properly collected by dust collectors, and environmental measurements confirm that there is no exposure to workers. In addition, materials spilled into the water during cleaning are separated in a sedimentation tank within the factory and disposed of appropriately as industrial waste. |
| Answer to specific info request 6:  The missing use for PFAS is 'industrial automation components and equipment'. Sub-uses are almost unlimited. Restricting or inhibiting the supply of these "industrial automation components and equipment" will adversely affect the manufacturing and process industries in the European Union. Fluoropolymers are often used in industrial applications such as the automotive, machinery and semiconductor industries. These polymers have been assessed as being of low concern (PTFE, FEP, PFA, and ETFE). These polymers have proven to be chemically stable, non-toxic, non-bioavailable, non-water soluble and non-migratory. For these reasons, in addition to factors such as safety, energy consumption and service life, fluoropolymers are also approved as materials for food contact and medical technology. The use of fluoropolymers is highly relevant to the whole industry, as a wide range of components and equipment are used to manufacture industrial machinery across the European Union. This machinery is used in the manufacture of almost all the essentials needed to support the daily lives of modern society. a. I don't have information on this topic. b. The main features of the PFAS materials used are their physical properties. Chemical resistance, temperature resistance and general mechanical properties uniquely provide the functionality required for many industrial automation components and equipment. Many applications in components and equipment cannot be satisfied by alternative materials, making corresponding industrial machinery and processes impossible. “Seals" (packing) are used in industrial machinery as sealing systems (sealing components) to prevent fluid leakage and intrusion of foreign substances from the outside. Since seals seal fluids, the materials used must have appropriate elasticity, so various elastomers and resin materials are used. In seals (packings) used under high-pressure conditions, seals tend to protrude from the overhang gap of sliding parts and are easily damaged. Therefore, "backup rings" are used in combination to fill the gap, thereby extending the life of the seal. Since the material of this backup ring must have adequate rigidity and elasticity, resin materials are mainly used. Fluorine rubber and PTFE, which are the subject of the proposed regulation, are used as important materials in the construction of various sealing systems, including hydraulic and pneumatic cylinders.　 【Fluorine rubber】 Fluorine rubber is used for seals that are used under high temperature conditions. Silicone rubber and HNBR are also available as rubber materials that can be used under high temperature conditions. However, silicone rubber and HNBR have significantly inferior mechanical strength and abrasion resistance compared to fluorine rubber, so they can be used for seals for fixed applications. Although it is possible, it is difficult to use silicone rubber, especially in reciprocating seals, so fluorine rubber is used instead.　 Furthermore, fluorine rubber is resistant to various fluids including acidic and alkaline solutions, so fluorine rubber is used not only under high-temperature conditions but also as a sealing material in environments with special fluids. 【PTFE】 PTFE is used as a back-up ring material as well as a sealing material because of its heat resistance and flexibility. PTFE is used as a material for backup rings as well as sealing materials. There are backup rings made of synthetic resins such as polyethylene and nylon, but these materials do not have any of the characteristics of PTFE, such as “heat resistance”, “flexibility”, and “low friction properties”. However, since it does not satisfy all requirements, it can only be used for limited purposes. Currently, it is difficult to establish an existing sealing system without a PTFE backup ring. c. I don't have information on this topic. d. There are currently no known alternative materials to fluoropolymers used in the industry to manufacture components and equipment for industrial automation. Since the development of alternative materials that meet the usage conditions and environment of regulated fluorine rubber and PTFE is extremely difficult considering the history of material development, the grace period for application of regulations to fluorine rubber and PTFE has been extended. I think this should be a special measure with no time limit. e. f. g. I don't have information on this topic. |

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| 8125 | Date:  2023/09/21 08:53  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  E.G.O. Elektro-Gerätebau GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Sector: Electronics, Household Industry, Uses: PTFE insulation of NTC in induction coils --> Use is not considered in restriction report. Therefore information are provided within point 3.6 |
| Answer to specific info request 6:  Description of use: Used in some induction coils of induction hobs. PTFE insulation is used for insulation of NTC-thermistor towards radiating heat from the ceramic glass during cooking. The NTC-thermistor is placed directly beneath the ceramic glass to detect temperatures, therefore high temperatures (above 250C°) occur. PTFE is used as insulation of NTC-wires and insulation sleeve around the NTC. a) Approximately 1.000.000 parts will be sold per year in the future, for that approx. 100kg PTFE is used b) Thermal stability to assure electrical insulation at recurring high temperatures. c) Wide range of B2B customers. PTFE insulation in induction coils is commonly used industry. d) Alternatives are in general available and are used in other induction coil series. But a redesign of the induction coil is necessary. A simple switch to other induction coils series is not possible due to functional reasons. Other coil series are not able to provide the same power/performance level in the final application, hence this is a blocking point for a specific category of cooking hobs. Furthermore, is the alternative material/construction associated with higher costs per part. A transition period of 18months would be hardly sufficient due to lifecycle test, approbation (safety relevant) for various product types, change of production and especially clearing the supply chain towards the final customer. |

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| 8126 | Date:  2023/09/21 09:00  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  E.G.O. Elektro-Gerätebau GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Sector: Electronics, Household Industry, Uses: FEP cable insulation in wiring of induction hobs --> Use is not considered in restriction report. Therefore information are provided within point 3.6 |
| Answer to specific info request 6:  FEP is used in Lin-Bus cable insulation in induction hobs. These cables connect touch controls with the generator. The cabling of touch controls goes near the induction coils. Due to the radiating heat from a pan/cooktop the operating temperatures require the use materials with high temperature resistance. Currently is technically assessed if alternative cable insulation are possible without negative effects on safety requirements. a) Approx. 4500km cable b) Heat resistance, mechanical strength, electrical insulation c) All customers of application d) - Technical alternatives with different wire routing to reduce temperature may be an option, but does not work in all cases due electromagnetic compatibility (EMC). Other cabling would require other/more openings in the shielding plate between inductor and generator which would cause EMC problems. Substitution with other cable insulation material is being assessed. Possible options are silicon or glass fiber insulation, but depending on temperature resistance and approval requirements. Especially in US approval requirements are strict when it comes to flammability. e) see d) evaluation of technical availability is performed f) A transition period of 18 months is not sufficient. As soon as alternative material is identified lifetime test take approx. one year. Afterwards approval must be granted by external agencies. If the new alternative material does not fulfill lifetime requirements or does not get an approval this procedure needs to start from the beginning. Some procedure may need to be done by our customers for the final application as well. Furthermore, the complete product portfolio (several assemblies/appliances) need to be changed and the complete supply chain need to cleared of FEP containing cable. In sum a transition period of 6.5 years EIF would be suitable. Cost are difficult to calculate. First of all, implementation costs for change of material, lifetime test, approval, change of applications and drawings, etc. are going into several 100.000€. Furthermore, additional cost for alternative insulation material will occur. Costs are depending on used material. g) We are confident, that a substitution is possible but not within 18 months! A transition period of 18 months would bear a high risk that no suitable alternative can be found, tested and approved. Therefore sales of induction hobs would need to be stopped and already produced hobs would need to be destroyed. Furthermore would a restriction in EU also affect our business with countries outside the EU, when PFAS containing parts can't be used anymore. Therefore negative long-term effects on market position and return occur when companies outside the EU can deliver products but we are not able due to the PFAS restriction. Consequently also negative impact on workforce are to be expected. |

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| 8127 | Date:  2023/09/21 09:17  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Liebherr-Werk Telfs GmbH  Org. country:  Austria | General Comments:  We are manufacturers of earth movement machinery (non-road mobile machinery) which are working tools to help build the houses, offices, factories, roads, railways and bridges… that serve citizens. We would like to make the following comments, related to our industry sector, on the restriction report: The PFAS restriction proposal may call the fulfilment of the objectives of the Green Deal into question and, if applied as is, would drastically affect our sector’s supply chains, halting the manufacturing of our products. The PFAS restriction proposal, if brought into force as is, would put the placing on the Single Market and the export of construction equipment, manufactured in EU-based plants, in jeopardy for several years. Therefore, we call upon the European Commission to ultimately take the most proportionate measures to safeguard our industry whilst fulfilling the EU Green Deal. As an interested party, we would like to submit the following recommendations to ECHA and the European Commission: 1. Anticipating that an 18-month transition period will be conducive to impeding our supply chains with durable and severe repercussions on the Single Market, in addition to putting at risk the EU Green Deal and its circularity objectives, we request ECHA to provide for transition periods of four to eight years in keeping with our industry’s specificities. On principle, applications of PFAS should be allowed until the full-scale availability of technically suitable, commercially viable and irrefutably safe alternatives can be demonstrated. 2. We call upon ECHA to level the playing field between industries that share supply chains and technologies and request ECHA to grant the construction equipment industry, at the very least, the same derogations for the applications of refrigerants as the ones granted to the automotive industry. 3. Similarly, we call upon ECHA to grant the construction equipment industry, at the very least, the same derogations for the use of PFAS in applications affecting the proper functioning related to its safety, its operators, workers/users, and goods in addition to proposing a 13.5-year derogation after entry into force. 4. We stand for an exclusion of fluoropolymers (including fluoroelastomers and polytetrafluoroethylene) from this restriction proposal or, at the very least, a 13.5-year derogation after entry into force for our essential fluoropolymers uses on O-rings, seals, coatings, hoses, clutch plates alongside brake friction disks. We invite ECHA to work on restrictions of high-risk PFAS instead of adopting the Dossier Submitters’ “one-ban-fits-all” approach. 5. In case of any fluoropolymers (including fluoroelastomers and polytetrafluoroethylene) restriction, we request a general 13.5-year derogation after entry into force for all other essential PFAS uses on O-rings, seals, coatings, hoses, clutch plates alongside brake friction disks. 6. Considering that the revision of REACh is likely to take years, we call upon the Commission to publish, at its earliest convenience, a Communication delineating the Essential Use concept and its methodology in future substance restrictions under REACh. 7. We stand for a cross-sector 13.5-year derogation after entry into force for uses of PFAS in Li-ion batteries. 8. Uses of PFAS in spare parts, remanufactured, refurbished, or second-hand products should benefit from a permanent derogation. |
| Answer to specific info request 1:  The earth-moving machinery that we manufacture is a complex product group designed for harsh conditions and an extended service life, regularly over 20 years. The proposed ban on PFAS affects our production process as well as our products in multiple ways. Please find below the sectors and (sub-)uses to which our comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9 & 2). - Applications of fluorinated gases: refrigeration, air conditionning in non-road mobile machinery. - Transport: sealing and gaskets applications, combustion engine systems, coating and finishings. - Electronics & semi-conductors: wires and cables, coating, solvents, cleaning, electronic components - Energy sector: batteries - Lubricants: low viscosity lubricants, solid/dry-film lubrication, release agents, greases. |
| Answer to specific info request 2:  We agree with Plastics Europe’s Fluoropolymers Product Group (FPG) who argued that concerns of persistence can be appropriately mitigated by regulating manufacturing and waste practices in lieu of a blanket ban[1]. Based on an industry-supported study, fluoropolymers should be differentiated from other PFAS as they meet the criteria to be classified as polymers of low concern due to their high molecular weight, narrow molecular weight distribution and negligible oligomer content in addition to their organic and inorganic leachability[2]. The study demonstrated that PTFE does not present any acute or sub-chronic systemic toxicity, irritation, sensitization, local toxicity on implementation, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombogenicity. It should be considered that in case of a non-derogation of spare parts/re-use/remanufacturing, recyclers might face a substantial increase of waste volumes from machinery and other products that can no longer be repaired adequately because of missing spare parts. This is jeopardising the objectives of the Green Deal. [1] https://fluoropolymers.plasticseurope.org/application/files/8716/7991/0281/21\_March\_FPG\_Statement\_on\_the\_PFAS\_REACH\_restriction\_report.pdf [2] Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, Buxton LW, Fiedler H, Seed J, Hernandez O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag. 2018 May;14(3):316-334. doi: 10.1002/ieam.4035. Epub 2018 Mar 30. PMID: 29424474. [Accessible from: https://doi.org/10.1002/ieam.4035] |
| Answer to specific info request 6:  REFRIGERANTS Refrigerants, such as R-134a and R-1234yf, are used for heating, ventilation and air conditioning (HVAC) systems. The construction equipment industry utilizes refrigerants (containing PFAS) to fulfil various health, safety and ergonomic requirements to cool down operator stations. These fluorinated gases (especially R-1234yf) present non-corrosive and non-toxic characteristics with a low global warming potential (GWP), zero ozone depleting potential (ODP) and a low boiling point. The EU regulatory framework already provides for the control and prevention of exposure, including leakage, in addition to requiring proper service personnel training. All currently available solutions are either intended to be banned or present an extreme risk to health and safety of the machine operator due to their flammability (e.g., ammonia, propane, and isobutane). First estimates by our industry foresee a 7-year timeframe needed to develop a commercially viable and available alternative. CO2-based air conditioning systems are being explored by the automotive industry, but the viability for production in the near future has not yet been demonstrated. For lack of drop-in substitutes for PFAS, our industry estimates that, upon identification of a suitable alternative, a 20 to 25-year timespan is needed to make any alternative substance operational across our complex supply chains. This alternative development process entails lengthy steps such as the revision of data collection and information exchange systems, training, formatting of information, testing, validation, and certification among others. Air conditioning Air-conditioning systems are vital to provide operators of construction machinery with a controlled temperature in the cabin, allowing them to operate machinery in a safe way without adverse effects to their health. There are currently no commercially viable alternatives meeting our HVAC system requirements. The continued usage of R134a or R1234yf is necessary. The derogation for those systems is crucial. Without derogation, our industry will have no choice but to place machines without air conditioning on the European Union market, which would be extremely detrimental to the health of operators. Therefore, the safe operations of the machine may be at risk due to an unhealthy and unsafe working environment. Earth-moving machinery sales would be seriously impacted both in the EU and in non-EU countries, as most markets require air conditioning for their operators’ comfort and safety. We stand for an extensive derogation period. As in most other sectors, engineering resources are scarce, hence the resources that will have to be mobilized to redevelop air-conditioning systems will adversely affect the development of battery-electric machines alongside other green transition technologies. Additionally, testing capacities of manufacturers and independent testing companies will be overloaded due to the new requirements which can result in unwanted delays in deliveries and in loss of business for the end user. The usage of F-gases in the machinery is not only needed for HVAC, but also for cooling batteries and electrical cabinets in the larger battery-electric machines. This application needs to benefit from a similar derogation as well. Lithium-ion batteries In the context of the electrification of our industrial machinery, including construction equipment and with the ever-growing demand for long-lasting batteries, it has become apparent that certain fluoropolymers will be instrumental in facilitating this cross-sector transition to zero-emission technology. The automotive industry as well as the construction equipment industry need lithium-ion (Li-ion) batteries for their electric vehicles and machines. This increased demand relies on gaskets for the electrodes of li-ion batteries. Certain corporate researchers surveyed the use of fluororesin made of PFA (Perfluoroalkoxy Copolymer), which is a co-polymer of PTFE, due to its electrolyte resistance, electrical insulation properties, climate resistance and low moisture permeability[3]. They found that PFA gaskets present a long-term reliability in the case of automotive Li-ion batteries. It is noteworthy that the European Commission’s Joint Research Centre (JRC) recently released a study that acknowledges the importance of fluoropolymers in the supply chains of strategic technologies and sectors in the EU[4]. Regarding Li-ion battery technology, the JRC interestingly classified two fluorinated polymers, PVDF (Polyvinylidene Fluoride) and PTFE, as precursor materials for battery components and key intermediate materials to produce battery precursors (cf. p.243). Polytetrafluoroethylene and expanded polytetrafluoroethylene were also identified, among other PFAS, as materials for electrolysers, data transmission networks and robotics. In addition, another fluorinated polymer, optical fiber cladding material, was singled out as processed material for data transmission networks alongside data storage and servers. [3] Liu J, Aoyama T, Tsuda H, Sukeagawa M. Long-term reliability evaluation of fluororesin gasket for electrode of automotive lithium-ion battery using simulation. COUPLED VIII : proceedings of the VIII International Conference on Computational Methods for Coupled Problems in Science and Engineering [Internet]. CIMNE; 2019. p. 269–79. [Accessible from: https://upcommons.upc.edu/handle/2117/190005] [4] Carrara, S., Bobba, S., Blagoeva, D., Alves Dias, P., Cavalli, A., Georgitzikis, K., Grohol, M., Itul, A., Kuzov, T., Latunussa, C., Lyons, L., Malano, G., Maury, T., Prior Arce, A., Somers, J., Telsnig, T., Veeh, C., Wittmer, D., Black, C., Pennington, D. and Christou, M., Supply chain analysis and material demand forecast in strategic technologies and sectors in the EU – A foresight study, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/334074, JRC132889. [Accessible from: https://op.europa.eu/en/publication-detail/-/publication/9e17a3c2-c48f-11ed-a05c-01aa75ed71a1/language-en] SEALINGS PFAS used: Fluoroelastomers : FKM - FMVQ - FFKM ; Fluoroplastics : PTFE - PFA - PVDF - ECTFE – PCTFE Key functionalities: chemical inertness, friction properties and resistance to a wide range of temperatures, so Fluorocarbon-based fluoroelastomers, such as FKM products, are used within systems with upper usage limit around 230-250°C, depending on the sealing material applied and which require strong (chemical) resistance. O-Rings FKM is the preferred method for sealing a wide range of fluids and gases. O-Rings are relatively low cost, durable and serviceable and are therefore used extensively in our products. As the complexity of products has increased, O-Rings have also had to adapt particularly in their physical characteristics considering pressure, temperature and chemical resistance. As an example, due to the addition of emissions reduction technologies, temperatures in and around engines and their ancillary components have significantly increased and, as a result, the requested target life for seals has increased accordingly. This has driven most manufacturers to transition to FKM over the years. If manufacturers were required to replace those seals with others made of inferior materials, there would be a drastic reduction in durability. Customers would be obliged to replace and rebuild at much lower hours, drastically increasing the workload for technicians and creating additional waste. There is no alternative polymer that has equivalent performance and durability on the market. Alternatives: PEEK, HDPE and PA have been identified for specific uses but are not suitable for every application, due to inferior performance. PEEK is significantly more expensive and is not a viable alternative for many applications. Substitution of PTFE and fluoroelastomers in static seals: Metal seals can be used in rare cases and are not suitable for many uses, notably for pressure equipment and long-term performance, because of inferior tightness performances that can conduct to leakages with risks of environmental pollution. Substitution of fluoroelastomers: No substitution solution for applications requiring resistance to extreme temperatures has been identified. More generally, applications requiring a combination of several PFAS properties do not appear to be substitutable. Depending on the application and system conditions, an FKM-based O-ring could have a functional performance life from 10 to 100 times longer than an NBR- or EPDM-based O-ring, which are currently the best performing non-PFAS replacement material. With the average life of a machine being 10k-40k hours, the lifecycle reduction has a significant impact on cost and waste produced. Viton™ seals The widely used Viton™ seals are made of Fluorine Latex (‘Kautschuk’) Material (FKM), which is a fluorocarbon-based fluoroelastomer. The closest material, in terms of temperature and chemical resistance, which is not a PFAS, is AEM/ACM, which has ~75°C less temperature resistance and a ~20% weaker oil resistance proving it to be not suitable for the harsh applications in construction equipment. It has become apparent that there are no viable alternatives available today. Any restriction on the use of FKM as a material will result in significantly reduced seal lifetime and higher risk of leaks. Press-in-Place Seals Most of these seals are FKM for the same reasons as FKM used for O-rings. Fuel Systems FKM is a recommended seal material in diesel and biodiesel fuels. As well as the other properties noted, FKM is able to better withstand degradation from exposure to fuel and this is particularly true of the more recent biodiesel blends which are favoured where decarbonization is being implemented. Other materials swell significantly and most, if not all, manufacturers switched exclusively to FKM in fuel systems over 20 years ago. Water Seals Water seals are used to seal the coolant passages on engine blocks. These are typically coolant resistant FKM (CR-FKM). This material is the only available option because the application requires a coolant resistant material that can also withstand high ambient temperatures (from the cylinder). Liner Seals Manufacturers use FKM and CR-FKM on cylinder liner seals as well. The upper liner (or filler bands) are typically CR-FKM, because they are exposed to high temperatures and seal coolant from the bottom side of the seal. Shaft Seals Some rotating shaft seals are also made of FKM because of the need for high temperature resistance. Crankshaft Seals These seals use a PTFE wafer as the main sealing lip on the crankshaft. To our knowledge, most if not all engine models use this type of sealing technology. There may be a few other types of crankshaft seals that do not use PTFE, but it would be a massive undertaking to design all new crank seals if PTFE would be banned. Reciprocating Seal Rings There is a family of PTFE rectangular shaped seal rings that are used with rubber energizers to seal reciprocating joints. PTFE is used because of its low friction properties. Lip Seals Coatings There is a family of machined lip seals made from PTFE billets that are used in brakes and transmissions as reciprocating seals again because of the low friction properties. A large percentage of highly durable O-rings (and most of the very high-volume STOR/ORFS O-rings) are coated with PTFE. This is done to reduce the friction when the O-ring is installed into the joint. FRICTION APPLICATIONS PFAS used: PTFE, PVDF, PCTFE, ETFE, FEP, THE-EFP, PVDF-HFP Key functionalities: Tribological properties (coefficient of friction, pressure-velocity limit, abrasion resistance and abrasion volume), extreme temperature and acids resistance, surfactants, improved resistance, antistatic agent, non-stick, resistance to aggressive chemical fluids and extreme temperatures fire resistance, anti-corrosion, insulation, non-wettability. Alternatives: No alternative solution has yet been identified. Most of the documents studied address the use of PFASs without focusing on the alternative materials that would meet the specifications of each sector. Substituting nickel PTFE seems impossible at this time. More generally, applications requiring a combination of several PFAS properties do not appear to be substitutable. In addition, solutions based on brass (with lead content) cannot be deployed or in a limited way because already regulated under the REACH and RoHS regulations.Substitution of PTFE for friction bearings: PEEK and PA are not satisfactory. Clutch Disks Friction disks for transmissions commonly use FKM compounds. FKM is preferred over other polymers, such as NBR, because of its superior temperature resistance. PFAS is used in a proprietary compound in high energy transmission clutch plates, and brake friction disc packs (e.g., large mining equipment) due to the high temperature requirements and cycles these systems face. Any known substitute would decrease the current life of the friction discs by 75%. Switching to this material will cause a redesign of transmission controls, cooling systems and recertifying brake systems. A new/replacement compound would reduce the life of the clutch, and friction disc plates by 75% which will require three additional replacements of the plates during the service life of the machines transmission and braking systems. LUBRICANTS PFAS used: Fluoropolymers (notably PFPE), HFE, perfluoroalkyl ethers/alkanes, n:2 FTO, PTFE as additive, perfluoroether Key functionalities of PFPE : resistance to extreme temperatures and harsh chemical conditions, very good oxidation stability, compatibility with oxidizing gases applications. Alternatives: Substitution in perfluoropolyether-based lubricants: Research is underway into new types of lubricant, such as those based on vegetable oils or ionic liquids. Other lubricants on the market are based on mineral oils, silicones, polyol esters or poly-alkylene glycol. However, the performance of these different solutions is inferior to that of PFPE. None of the existing alternatives is efficient as PFPE lubricants. Ionic solutions are still at an early stage of research at the moment. GENERAL COMMENT ON PROPOSED 18-MONTH TRANSITION PERIOD In view of the amplitude of this restriction proposal, a transition period longer than the proposed 18-month timespan would enable the construction equipment industry to continue developing sustainable substitutions, placing safe and durable products on the market and, ultimately, reducing waste generation. As recently proposed by Orgalim1, representing Europe’s technology industries, transition periods of four to eight years after entry into force would facilitate transition and mitigate possible socioeconomic impacts. |
| Answer to specific info request 7:  We would like to highlight the necessity of a permanent derogation on essential uses of PFAS in spare parts, remanufactured, refurbished, or second-hand products: a) Spare parts All our products have extended lifecycles, regularly over 20 years. This longevity is key in the purchasing decisions of our customers, and we have extensive spare parts and service networks that have been developed over many years to foster repair of products. Spare parts constitute an important area of our industry and without a spare part derogation, this will adversely affect both our business in Europe, including loss of full-time equivalents (FTEs), and the possibility to simply and quickly repair machines already on the market. It would be impossible for us to develop and supply full component assemblies including alternative sealing technologies (even if they would be available) for these older machines that today would be repaired through the relatively simple replacement of a seal or O-ring. Our machines today work in many applications including civil construction, mining of essential minerals, infrastructure and waste treatment. If the users of our machinery are deprived of spare parts to maintain their equipment, the impact on their business would be detrimental. With an extensive prohibition of PFAS, and in the absence of drop-in alternatives without PFAS, the ‘end-of-life’ of construction equipment will be fast-tracked and its servicing, repair, and maintenance will be put in jeopardy. Remanufacturing, refurbishing, servicing, maintenance, and repairs are instrumental in the EU Green Deal and circular economy. b) Remanufactured, refurbished, or second-hand products In the context of the inter-institutional negotiations on the Proposal for Ecodesign for Sustainable Products Regulation (ESPR) and notably the negotiations between the European Union and India on a future trade agreement, the PFAS restriction proposal is at odds with the remanufacturing, refurbishment, and wider incentives for circular economy that the European Commission has been developing over the last few years. As an exemplification of this policy direction, the Commission tabled a Proposal for a Directive on common rules promoting the repair of goods earlier this year. If adopted, this directive would apply to the repair of goods purchased by consumers in the event of a defect of the goods that occurs or becomes apparent outside the liability of the seller. The consequences of a PFAS prohibition on the aftermarket across industries should not be underestimated. Given that many engines would have to be withdrawn from the market, the supply of second-hand products would severely shrink and thereby incentivize the disposal of products. The coherence of the EU regulatory framework would thus be undermined. In addition, the socio-economic costs of engine and other products shortages should not be downplayed. The subsequent price increases of products, usually subject to remanufacturing and refurbishment and placed on the aftermarket, will further highlight the negative effects of this PFAS restriction proposal. |
| Answer to specific info request 8:  See our answer to point 7 |

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| 8128 | Date:  2023/09/21 09:18  Content:  Hazard or exposure  Environmental emissions  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Information describes business interests. It contains proprietary and company identifiable information. | General Comments:  - |
| Answer to specific info request 1:  Please see the attached document. |
| Answer to specific info request 2:  Please see the attached document. |
| Answer to specific info request 3:  Please see the attached document. |
| Answer to specific info request 4:  Please see the attached document. |
| Answer to specific info request 5:  Please see the attached document. |
| Answer to specific info request 7:  Please see the attached document. |
| Answer to specific info request 8:  Please see the attached document. |
| Answer to specific info request 9:  Please see the attached document. |

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| 8129 | Date:  2023/09/21 09:29  Content:  Scope or restriction option analysis  Hazard or exposure  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:  We are a manufacturer of medical devices and care for the wellbeing of our patients in every aspect. This covers our direct role as a provider of instruments and products to facilitate diagnostics and therapy. But also as part of the society and individual citizens we care for the environment and are concerned about chemicals accumulating in nature and humans. As medical device manufacturers we are part of an industry with long and complex supply chains. From what we know it is very likely that among the many parts we purchase from our direct suppliers there are parts that either contain PFAS or where PFAS are involved during the manufacturing process. During the consultation period it was not possible for us to perform a complete and thorough analysis, which of our parts and components would be affected by a potential ban of PFAS. We as a small enterprise, order very low volumes of materials compared to consumer product companies or the automotive industry, but nevertheless require high quality products and many proofs for regulatory purposes. This results in a very low impact and priority with our suppliers. As a manufacturer we do not purchase PFAS directly. As the knowledge which parts, components or processes involve PFAS often is not available at our direct supplier but is only available further upstream in the supply chain, gathering information is a time consuming and sometimes futile endeavor. This absence of support is hard to show as supporting evidence. Publicly available information show that metal parts (e.g. with friction reduction surface treatment), certain polymer parts or electronics containing PTFE, PVDF, PFA or PFPE or using these polymers during manufacturing would be subject to the ban. This will result in major efforts to replace these materials, while even the major chemical companies do not provide or promise replacement materials in the foreseeable future. Even when those would be available at some point in the future the effort to introduce the replacement within engineering is calculated by us to be 2 to 3 years with further 3 years to validate their application in medical devices. The necessary change control and gathering of clinical data is strongly enforced by the notified bodies following EU regulation. As there are presently no replacement materials available the cost of engineering and validation cannot be calculated to be presented as supporting evidence. It is very likely that following a PFAS ban as planned many of the medical devices listed below under “1 Sectors and (sub-)uses” will be discontinued and be no longer available for patients benefit. Even with the maximum derogation time a timely replacement of PFAS and uninterrupted availability is far from sure. For us as an SME medical device manufacturer it is impossible to give detailed substantiated information on the alternatives and efforts needed after a complete ban of PFAS. However, the very likely consequence will be a discontinuation of medical devices that are in daily use all over Europe! |
| Answer to specific info request 1:  Sector: Medical devices (Annex E.2.9.) We request that - MR diagnostic incubator system - neonatal coils (head and body) be newly added to derogation as missing use. Our company is where MRI meets neonatology. The globally unique MR diagnostic incubator system allows newborns and premature babies to be transported from the pediatric intensive care unit directly to the MR room. There they are examined using optimal, non-invasive magnetic resonance imaging. The baby is protected throughout the entire transport and examination in the life-sustaining MR incubator, which also constantly controls the temperature and humidity. In the past, it was almost impossible to examine premature babies using MRI. As a rule, they rely on the special protection of an incubator and should not leave it. With the MR diagnostic incubator system, this gap in pediatric radiology could be closed. The child is already placed in the neonatal intensive care unit with the appropriate coil in the MR incubator - the time-consuming and stressful repositioning in radiology is no longer necessary. During the entire examination, the patient lies protected in the MR incubator and is looked after by the neonatologist during the examination. The advantage of the MR incubator is that almost the entire body can be scanned using different coil combinations. After the measurement, the radiologist evaluates the MRI images together with the pediatrician and can thus immediately initiate further measures. |
| Answer to specific info request 6:  As already stated in the general comments, the medical devices listed under 1. Sectors and (sub-)uses are very likely affected by a PFAS ban, as they consist of parts and materials listed in many other sectors covered in the Restriction Report e.g. electronics or coated metal parts. Missing these products will very likely lead to a discontinuation of the listed medical devices after a PFAS ban. Even when replacement materials for these parts and materials would be available at some point during a derogation period, we as a medical device manufacturer would have only the remaining time of said derogation period to engineer and validate the use within our medical devices. The current enforcement of the medical device regulation is very clear regarding the necessary proofs. We therefore request the exemption or at least the maximum derogation period of 12 years for the products listed under 1. Sectors and (sub-)uses on the basis of the negative impact on patient care if said medical devices would be no longer available due to the non- availability of necessary pre-products and the time-consuming revalidation after technical changes. |

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| 8130 | Date:  2023/09/21 09:43  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:  Industry or trade association  Org. name:  Assogalvanica  Org. country:  Italy  Attachment: | General Comments:  The following comment is provided as text in the specific form fields and as attachment for better reading. |
| Answer to specific info request 1:  Sector: Metal plating and manufacture of metal products Sub-use: Hard chrome plating |
| Answer to specific info request 7:  The use of PFAS as fume suppressant is marked for reconsideration after the consultation. With this comment we would like to strengthen the justification for the derogation as we consider that there is not a technically and economically feasible alternative to the use of PFAS as fume suppressant in hard chrome plating. It is crucial to note that PFAS are used in very limited quantity, nonetheless they are essential for the protection of both workers' health and the environment. The following data provide further support for our argument. --- a) Annual Tonnage and Emissions of PFAS In consideration of the PFAS draft regulation for its use as a fume suppressant in hard chrome plating, we offer the following estimates based on available data: 1. Annual Tonnage of PFAS use: The annual usage in Europe of PFASs substance is estimated between 6 and 9 metric tons. This figure represents the total quantity of PFAS utilized across all European companies engaged in hard chrome plating. This estimation is calculated as following: 1.1. The specific usage of PFAS substance on unit of chromium trioxide consumed (used tons of PFAS on used tons of chromium trioxide), has been derived from the real world usage data from hard chrome facilities. The specific usage of PFAS ranges between 0,0010 and 0,0015 tons/tons of used chromium trioxide. 1.2. The European annual usage of PFAS has been calculated multiplying the specific usage of PFAS by the estimated annual usage of chromium trioxide as estimated for Europe by the CTACSub authorization documents of hard chrome use (6.000 tons per year). Even though this data originates from a 2015 document, due to the market remaining relatively unchanged, the estimated annual usage of chromium trioxide, which is about 6.000 tons per year, is still considered valid as of 2023. 2. Emissions of PFAS are categorized as follows: 2.1. Water Emissions: The quantity of water emissions varies depending on whether the company employs a closed-loop water system or not. For companies not using a closed-loop water system, PFAS emissions typically occur as a byproduct of the plating process, where the drag-out from the plating tank flows into the rinsing tank, and then through the company's wastewater physio-chemical treatment plant. Here, if activated carbon is used, some of the PFAS will be adsorbed by the carbon and will eventually be treated externally as waste. If no activated carbon is used, PFAS will be discharged into the sewage system. Usually, due to the specifics of the process, most of hard chromium plating shops adopts a closed-loop water system with no waste water emissions. 2.2. Waste Emissions: Waste emissions also differ based on the water system employed by the company. Here are the main types of waste emissions: 2.2.1. Exhausted Concentrated Rinsing Water: Following the plating process, parts that have been coated with a chrome plating electrolyte containing PFAS are rinsed in a non-renewing water bath. Once this rinsing bath reaches its capacity and becomes exhausted, it is handled as waste and sent to external waste treatment facilities. This solution is usually concentrated before disposing to reduce its volume and minimize waste. 2.2.2. Eluate from Deionized Water Resins regeneration: In companies using a closed-loop water system, the rinsing water containing PFAS is treated by DI resin, typically preceded by an activated carbon treatment. This is because the presence of organic pollutants can compromise the efficiency and regenerability of ion exchange resins, hence the use of activated carbon. If activated carbon is not used, PFAS is captured by the DI resin. The spent DI resin may be treated within the plant or externally. However, the eluate containing the PFAS will become waste and treated externally. 2.2.3. Carbon used for Absorption: When activated carbon is used (in either type of water system), it will absorb PFAS. This spent carbon is usually disposed of as waste and generally incinerated, a process that destroys the PFAS, thereby helping to reduce the environmental impact. 2.2.4. Spent Bath: These wastes, which contain PFAS, result from the disposal of spent hard chrome plating baths. The frequency of the disposal, that may be total or partial, of the bath is very low, usually ranging from 3 to 10 years. The disposal depends on the accumulation of pollutants of the plating bath during the plating operation. The spent baths are disposed to authorized waste treatment facilities. --- b) Key Functionalities Provided by PFAS: PFAS plays an essential role as a fume suppressant in hard chrome plating primarily due to its ability to reduce surface tension. This characteristic significantly curtails aerosol emissions during the plating process, enhancing both worker safety and environmental protection. PFAS based fume suppressants have been used in hard chromium plating for more than twenty years and the management of this kind of suppressants is easy and well established. A critical aspect to highlight is that PFAS surfactants are the only known surfactants capable of withstanding oxidation by chromic acid, a common constituent in hard chrome plating solutions. This unique resistance allows PFAS to maintain its effectiveness over time, unlike other surfactants which would degrade in such conditions. The use of other surfactants that degrade under such conditions could pose unacceptable risks to workers as they could fail to adequately suppress fumes, leading to potential health hazards due to increased aerosol exposure. Therefore, PFAS surfactants provide a reliable, long-lasting solution for aerosol suppression in hard chrome plating processes. This unique characteristic, is the primary reason for its widespread use within the industry. --- c) Number of Companies Affected: Current data indicates that at least 650 European companies involved in hard chrome plating, which utilize chromium trioxide and likely PFAS-based fume suppressants, could face potential operational disruptions due to any future limitations on PFAS use. This data is primarily derived from companies that have either notified their use of chromium trioxide for hard chrome plating or obtained their own authorization for the same. --- d) Availability, Technical and Economic Feasibility, Hazards, and Risks of Alternatives: Currently, alternatives to PFAS as a fume suppressant in hard chrome plating are extremely limited in the market. There is only one known supplier who has developed a potential alternative using non-fluorinated surfactants. However, while this alternative does exist and is utilized to some extent, it has not been extensively tested and it’s still in the early stages of adoption. This potential alternative also presents technical challenges and potential risks. Accurate and constant monitoring is required for effective use, which may not be feasible for all companies given their resources, expertise, or the scale of their operations. Moreover, it has been reported that maintaining adequate worker protection is challenging due to the complicated operation of control and replenishment necessary for this alternative. Given the current state of development and the challenges presented by the sole potential alternative, it's anticipated that there could be significant shortages in the supply of effective alternatives if a restriction on PFAS use were to be implemented in the short term. Further research and development are needed before a technically and economically feasible alternative with comparable efficacy to PFAS could be widely available and adopted. --- e) Status of R&D Processes for Finding Suitable Alternatives: Most of the companies operating within the European hard chrome plating industry are SME enterprises, meaning their resources to explore and develop alternative substances to PFAS are significantly limited. Currently, our understanding regarding the progress of R&D activities in the sector to identify viable alternatives to PFAS in hard chrome plating is quite restricted. The scale of these R&D initiatives, in terms of duration and financial commitments, remains unclear. Similarly, projected timelines for introducing substitutes, inclusive of acquiring any requisite certifications or regulatory approvals, have yet to be defined. In conclusion, it's evident that a substantial amount of work is still required in the exploration and incorporation of PFAS alternatives within the hard chrome plating industry. --- f and g) Substitution technically and economically feasible The following sections, namely (f) and (g), are designed to address two distinct scenarios relating to the potential substitution of PFAS in hard chrome plating. Scenario (f) explores cases where substitution is technically and economically feasible, but more time is needed for the transition. In contrast, scenario (g) considers cases where substitution is not technically or economically feasible. It is important to note, however, that at present, while there is an existing alternative to PFAS, it is not extensively adopted and its feasibility is not yet conclusively proven, as stated before. Furthermore, it remains uncertain whether other alternatives will emerge in the near future. The complex nature of this situation necessitates a comprehensive approach to addressing the matter, which is why both scenarios are detailed below. --- f) For cases in which substitution is technically and economically feasible but more time is required to substitute: f1) Type and Magnitude of Costs Associated with Substitution: Providing an accurate estimation of the costs associated with replacing PFAS with the currently available alternatives is complex at the moment, especially considering that there is only one known supplier of this alternative. This monopolistic scenario could create potential price and supply chain risks. It's only after the alternative has been completely developed, commercialized, and competition introduced in the market, that we'll be able to make a more precise assessment of the initial implementation costs, ongoing operating costs, and market dynamics. f2) Time Required for Completing the Substitution Process: Our best estimate for the total time required to replace PFAS, which includes all necessary testing, implementation, validation, and obtaining necessary regulatory approvals, ranges from 4 to 10 years. It is important to note, however, that this is an estimate and the actual timeline could vary significantly depending on various factors including market conditions, the progress of research and development efforts, and regulatory processes. Moreover, it is crucial to acknowledge the inherent uncertainty in this process, as there is always a possibility that a technically and economically viable alternative may not be found. f3) Possible Differences in Functionality and Consequences for Downstream Users and Consumers: A paramount concern regarding the potential replacement of PFAS is its impact on worker safety and environmental protection. PFAS plays a crucial role in suppressing aerosols of chromic acid, which significantly reduces exposure risks for workers and also limits emissions into the environment. Any alternative that is less effective at suppressing aerosols could potentially increase workplace health hazards and environmental risks. Therefore, the presence of PFAS not only serves as a safety measure for the workers but also acts as a critical control to minimize environmental contamination. This highlights the importance of comprehensive testing and validation of any proposed alternatives to ensure they can provide the same level of worker protection and environmental safety. Furthermore, it's crucial to note that if an alternative doesn't offer an equivalent level of safety, or introduces different exposure scenarios, it will invalidate the current authorization for the use of chromium trioxide under the REACH regulation. Such a development could necessitate the suspension of plating production, leading to significant implications for the sector. Moreover, implementing a closed system with Local Exhaust Ventilation (LEV) using no fume suppressant is not a viable alternative either. Although this approach might seem to address worker safety concerns, it will lead to increased emissions to environment, posing higher risks to the air and the overall environment. Hence, any substitution must consider both human safety and environmental impact to ensure sustainable operations. f4) Benefits for Alternative Providers: At this point, the potential benefits for providers of PFAS alternatives are uncertain and may depend on various factors such as market demand, pricing, and regulatory developments. Furthermore, the fact that there is only one known alternative supplier creates a challenge to the alternative providers market, since the existence of a monopoly offers no competitive advantage. More study and market analysis are required to gain a comprehensive understanding of this aspect. --- g) For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors: g1) Impact on Companies: If substitution of PFAS is not technically or economically feasible, the potential socio-economic impacts on companies within the hard chrome plating sector would be considerable. The use of chromium trioxide, a key element in this sector, is subject to authorization under the REACH regulation. This authorization depends on an assessment of the chemical risks associated with its use, which is significantly minimized by PFAS fume suppressants. The inability to find a viable alternative to PFAS will increase the risk to workers, will invalidating the authorization. In such a scenario, companies may be forced to cease operations, leading to severe socio-economic implications, including job losses and impacts on related industries. g2) Impact on Consumers and Other Affected Actors: The ramifications would be equally significant for consumers and other stakeholders. Hard chrome plating is a crucial surface treatment for a wide range of applications, which currently lack viable alternatives. If operations were to cease due to a lack of a feasible PFAS substitute, it could considerably impact European industry and consumers, potentially leading to a decrease in product availability and an increase in costs. g3) Annual Value of EU Sales, Profits of the Relevant Sector, and Employment Numbers: The inability to find a viable alternative to PFAS as a fume suppressant, leading to the invalidation of the authorization for the use of chromium trioxide for hard chrome plating, can have extensive social and economic impacts. These impacts are multi-tiered, affecting suppliers of chromium trioxide, hard chrome platers, various industries that rely on hard chrome plating, and ultimately the customers. Economic Impact: The following data are taken from the Socio-economic Analysis carried out by the Chromium Trioxide Authorization Consortium (CTAC) , and annexed to the Application for Authorisation for Use 2, functional chrome plating, submitted by the CTACSub . Economic impact on suppliers of chromium trioxide. If hard chrome plating were to be discontinued, the expenses for raw materials, including chromium trioxide, and energy would plummet, leading to an estimated loss of €648.72 million, considering the NPV of future expenses over 12 years. Economic Impact on Hard Chrome Platers: The direct impact on hard chrome platers would be severe. With at least 23,205 employees potentially losing their jobs, the sector could face a severe downturn. The estimated loss, considering the NPV of future payments of wages over 12 years, is a staggering €7,939 million. Economic Impact on Industrial Companies Using Chrome Plating: The hard chrome plating sector underpins many other industries, including automotive, aerospace, defense, and heavy machinery. If hard chrome plating were to cease, these industries could face significant disruption, potentially causing job losses, production delays, and cost increases. Economic Impact on Customers: Customers may face the repercussions of these changes in the form of decreased product availability and increased costs. These impacts could affect product affordability and availability, leading to reduced consumer choice and potentially higher prices. Wider Economic Impacts: Beyond these direct impacts, there would also be broader economic implications, including a reduction in taxes paid by affected sectors, adverse impacts on economic development as the European supply chain for surfaces treated with chromium trioxide relocates to non-EEA countries, and potential quality and security concerns associated with increased dependency on imported parts and components treated with chromium trioxide. |

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| 8131 | Date:  2023/09/21 09:43  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Netherlands  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  This document revises 80c792df-cf6c-4ed2-bb24-44e6db586415 | General Comments:  Please refer to the confidential attachment in section V. |
| Answer to specific info request 1:  Please refer to the confidential attachment in section V. |
| Answer to specific info request 2:  Please refer to the confidential attachment in section V. |
| Answer to specific info request 5:  Please refer to the confidential attachment in section V. |
| Answer to specific info request 6:  Please refer to the confidential attachment in section V. |
| Answer to specific info request 7:  Please refer to the confidential attachment in section V. |

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| 8132 | Date:  2023/09/21 09:51  Content:  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment: | General Comments:  We agree and supports the statements made by JVMA on the issues of proposed restriction,as per attached in Section Ⅳ. |

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| 8133 | Date:  2023/09/21 09:52  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |