**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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| 4564 | Date:  2023/06/15 12:44  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 1:  We believe that pfas as used by industry today do not cause the damage for which they are at risk of being banned |

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| 4565 | Date:  2023/06/15 13:38  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  No confidential information is included | General Comments:  The Etienne Lacroix Group is a pyrotechnic systems Integrator, providing applications to the defence in particular with its subsidiary LACROIX located in the south of France.  A short presentation of the company and the general comment in response of this public consultation on the proposed restriction for PFAS are provided in the section IV.  This general comment was written by several companies, all members of the French Land Defence and Security Industry Association (GICAT). These companies have two main common points: the Pyrotechny and its applications in the defense field. They have been working together in a REACH working group since 2009. |
| Answer to specific info request 1:  The Annex XV restriction report version 2 does not cover relevant nor essential uses of fluoropolymers in the critical sector of « the defence » . In annex A, table A.1. Pyrotechnics and Defense Industry are mentioned as uses not researched in details. The target of LACROIX’s reply is to give more details on this sector and on a specific sub-use described below. Sector : Defence Use: a complete range of self-protection pyrotechnic systems for airborne applications. Sub-use: Manufacture of pyrotechnic compositions Manufacture of pyrotechnic compositions integrated in passive countermeasures systems to protect aircrafts against every threat. A range of flares and decoys are designed to protect combat jets (Mirage 2000, Rafale, Super Etendard) transport aircrafts (C130, C160, A400M) and helicopters (Puma, Super Puma). The current type of pyrotechnic infrared flares used to cover military applications is a composition magnesium, Teflon®, Viton® (MTV). The paragraphs below explain why Teflon® and Viton® are essential to maintain the capability of our armed forces. Infrared flares are pyrotechnic devices which emit a defined intensity of radiation in the IR region of the electromagnetic spectrum in addition to visible radiation. When ejected from an aircraft, the flares present a more attractive IR signature than that of the target and thus decoy the missile seeker away from the aircraft. The decoy flare emission should be larger than that of the aircraft in the spectral waveband of operation of the IR missile seeker so that the decoy becomes a prominent target for the missile. The targeted aircraft can protect itself from an IR missile attack by ejecting IR decoy flares. Each decoy flare is design to protect one type of aircraft, which is equipped by a specific launcher. Without this protection, no aircraft should be allowed to take off. For the first time in 1968, literature refers to the use of magnesium/PTFE mixtures in infrared decoy flares and gives details on caloric data and ignition sensitivity (Military and civilian Pyrotechnics, from ELLERN H. (1968). Over the years, improvements have been made in terms of performance and safety of the MTV decoy flares, which are still the most widely used flares. Why MTV formulations have to be considered as an essential use of fluoropolymers as PTFE and VITON® ? • To obtain the best performances of the flares : The performance of the flares invariably depends upon both the design and chemical nature of the IR-producing formulations. Parameters such as shape, size, weight, burning characteristics and IR output play an important role at the time of selection of a suitable formulation for a specific purpose. In particular, the IR output of a pyrotechnic formulation depends on the nature of its combustion products, their concentration in the flame, their emissivity and flame temperature and mass burning rate. The particularity of the MTV formulation is its emission of a radiant energy partly in the IR range and partly in the visible range with a minimum amount of smoke. The main reaction on combustion of magnesium with PTFE is shown in the equation below: 2nMg + -(C2F4)n-  2nMgF2 + 2nC = 23 Kcalg-1 The heat generated heats up carbon black to a temperature  2200°K, yielding radiant emittance values comparable to those of a black-body. Thus MTV spectral distribution displays the peak maximum at 2,0 µ and strong emission bands at 4,3 µ due to carbon dioxide. MTV formulations emit a high order of IR intensity because of the presence of fluorine therein. The last important point is that the MTV formulation does not produce oxygen and does not react with the ambiant air to generate gas as CO and CO2. (High Energy Materials – propellants, explosives and Pyrotechnics » from Jai Prakash Agrawal (2010)) • To assure a good ageing of the flares : The shelf-life of an ammunition is about 10 to 15 years. It means that the pyrotechnic composition must be very stable over time in hard environmental conditions (high and low temperatures, humidity, vibrations, …). Fluoropolymers are chemically very stable over time and fullfill their mission during the entire life of the ammunition. In addition, the proposal of restrictions on PFAs concerned also the placing on the market of articles which contains 250 ppb of PFAs. Ammunition and pyrotechnic components are considered in majority as articles. Some of them are only a part of a complex system, integrated later by our customers to be placed on the market. Another consequence of the restriction is that the ammunition and/or pyrotechnic or not components already in stocks of our customers (in particular of the DGA in France) can no longer be used after the date of application of the restrictions and have to be destroyed by fire. |
| Answer to specific info request 2:  Production site : First and foremost, the production sites of MTV formulations are often located in more remote regions, a combination of a large space and the low urbanization of rural areas. It is necessary to maintain suffisant regulatory hazards zones between the population outside the production site but also between each building of the production site depending on the type of activities realized (production, storage, transport, testing areas…) and the quantity implemented. Manufacture : Processing of magnesium Teflon® Viton® (MTV) or magnesium Teflon® (MT) : Several types of granular PTFE are used to produce about more than 40 different versions of MTV formulations. • Production process of MTV formulations. The flow chart of MTV flare production line (Metal fluorocarbon based Energetic Materials, First edition, Ernst Christian Koch) is presented in a document called "Production process of MTV" provided in section IV. It starts with the weighting out the amounts of PTFE which is granular (the average particle size is between 100 to 800 µm). The weighting out PTFE and VITON do not generate dust nor waste. In conformity with the study of safety for each operation of the production process approved by the french legal authority, the filling capacity of the blender (batch size) is few kilograms of pyrotechnic composition. VITON® is used as a binder in the formulation and dissolved in acetone. The viscous solution is introduced in the blender. The mixture is realized in wetted conditions with no generation of dust and in specific working places with strong walls, where operators are forbidden for safety reasons. They are not exposed to chemicals. The granulated composition is pressed into its final shape with molding tools. The drying of the composition is realized in an oven but not completely, also for safety reasons. A table which sums up the safety information at each working place of the process is presented also in the document called " "Production process of MTV" . The manufacturing of pyrotechnic formulation is regulated by plenty rules and regulations to protect the employees against a pyrotechnic hazard. Collective protection (screen, strong walls, automatic process), and personal protection equipments (Fire protective clothes, leather gloves, glasses, conductive safety shoes) are ever mandatory to be safeguarded in the case of an accidental ignition of the composition. |
| Answer to specific info request 3:  The flares compositions are released over a wide geographical area, both from a perspective of spreed of travel of the aircraft and the altitudinal variations. Ernest Koch has described the manufacture of toxic products of combustion of MTV and points out that the most toxic possible by-products (e.g. HF and MgF3) are calculated to be released at low concentrations due to the speed and trajectory of the aircraft and dispensing system (Metal fluorocarbon based Energetic Materials, First edition, Ernst Christian Koch). In particular, it ought be noted that HF is lighter than air and is less likely to « settle » (Energetic Materials and Munitions - Life Cycle Management, Environment Impact and Demilitarization » by Adam S. Cumming and Mark S. Johnson). End of life of the flare : Concerning PTFE and VITON® : No waste from the processing production of MTV : very, very low quantity of fluoropolymers is sent to be incinerated by a permitted industrial waste facility per year. These polymers have no shelf life to be used. In consequence, they can be ever kept. Concerning the MTV composition : pyrotechnic compositions are mandatory destroyed by fire on a specific outdoors area in the production site. This rarely happens. Never more than 100kg of fluoropolymers per year. As decribed by Ernest Koch, MTV will generate hydrogen fluoride and metal fluorides as magnesium fluoride and carbon soot as part of smoke formation. Ernest Koch states the important fact that in the open air, the dispersal of these products is much greater than in enclosed spaces. |
| Answer to specific info request 4:  Manufacture of MTV not concerned by the recycling. |
| Answer to specific info request 6:  a - Sector of defense - Sub-sector: Pyrotechnic systems integrator Use: a complete range of self-protection pyrotechnic systems for airborne applications. Sub-use: Manufacture of pyrotechnic compositions Annuel tonnage: less than 5 tons of PTFE and VITON Annuel emission: very low emission (no dust, no waste of raw material) - about 100 kg are eliminated with the wastes of pyrotechnic compositions (see details in paragraph 3) b - Information are provided in detail in the paragraph 1of this section. c - In France, LACROIX is the only industrial to provide the Armed Forces with a complete range of self-protection pyrotechnic systems using MTV. There is only one competitor in Europe. d - Up to now, there were no restriction on fluoropolymers which are not classified for a hazard for the health or for the environment. Finding an alternatives for MTV compositions was never identified as a priority. No study was conducted to find alternatives. Fluoropolymers are the most consistent/unique choice of material from 1970’s. e - The time expected to be required for substitution (including any relevant certification or regulatory approvals) : More than 25 different ammunitions adapted to different threats and to different IR signatures of aircrafts and helicopters exist today. For each one, the formulation of the MTV composition is adapted (rates and types of magnesium (atomised or granular), type of PTFE (free flowing, recycling, several granulometries). So, it is not one but many alternatives that must be found to meet all the required properties. In the case of alternatives found, the usual time to qualify a solution in one ammunition is around 8 years. The substitution will be not considered as a minor modification. In consequence, all the performances have to be tested. f - No study conducted to answer to this hypothesis. g - Economic impact of non observance of custumers’s contracts : A direct cost : In the case of the restriction on fluoropolymers shall apply 18 months from the entery into force, the impact on the annual sales turnover of LACROIX in the air sector would be estimated as > 70 %. This data is calculated with LACROIX knowledge of the sales planned from 2027 for the French forces and exports to other forces. It is stated that LACROIX will have to pay at least 10 or 20 % of the value of the committed market to repair the damage of the non-observance of the contracts. Indirect cost : The non-respect of the contracts or the tacit engagements to supply with the « consumable » would be an unmeasurable impact on the reputation of LACROIX and its future markets. Loss of employment : 20 to 50 employees from the production and support services. |

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| 4566 | Date:  2023/06/15 14:18  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  FUJIKO,We are manufactured and sold as a mold release film for silicone adhesives. If this becomes unusable,slicone adhesive film cannot be produced. Silicone adhesive film is used in semiconductors,electronics,patches,special packaging materials,etc, and is a material that has excellent heat resistance,weather resistance,and flexibility, and the release film is also a material that cannot be replaced. |

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| 4567 | Date:  2023/06/15 15:03  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  Switzerland  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |

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| 4568 | Date:  2023/06/15 15:09  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  ITM Power Plc.  Org. country:  United Kingdom  Attachment:  <redacted>  Privacy statement:  Protection of commercial interest and intellectual property | General Comments:  Through extensive material testing and research into alternatives to PFAS presented in the confidential document, ITM Power Plc. has concluded no alternative material is proving capable to replace fluoropolymers for PEM water electrolyser application. Fluoropolymers can’t be surpassed. Claimed alternatives are alarmingly unconvincing given ITM’s own extensive knowledge and research into this. They make selective claims based on individual properties rather than a necessary wider group of properties. Those facts are clear and obvious to engineers and scientists at ITM POWER Plc. ITM POWER Plc. therefore seeks an exemption. PEM electrolysis breaks up C-F bonds. Multiple references prove this. Detailed analytical chemistry results prove no PFAS from the EU ‘targeted 20’ list are present at any point of ITM product lifecycle and there is no detectable ‘Total’ PFAS presence as attested by an experienced independent laboratory in solid absorbents or liquid stream of ITM products. At the end of the closed system Lifecyle no detectable PFAS is present in the disposal process also analyzed and this process is imperative due to the presence of valuable metals. |
| Answer to specific info request 1:  Hydrogen from PEM electrolysis can provide up to 75% CO2 industry abatement from carbon intensive Hydrogen production from steam methane reforming. This can affect multiple sub-sectors as published by Technology University of Munich 'Lifecycle assessment of proton exchange membrane water electrolysis in future energy systems' Sector concerned are: Decarbonising fertiliser, Decarbonising steel, Decarbonising glass, Hydrogenation, De-sulphurisation, Hydrocracking Alternative fuels to decarbonize transport SAF, Sustainable Aviation Fuel Etc... |

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| 4569 | Date:  2023/06/15 15:25  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  The use of non-stick coatings is restricted by the ban. These non-stick coatings are indispensable from a technical point of view. |

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| 4570 | Date:  2023/06/15 15:45  Content:  Scope or restriction option analysis  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  CP Pumpen AG, CH 4800 Zofingen  Org. country:  Switzerland  Attachment:  <redacted>  Privacy statement:  the attachment includes business data of our company | General Comments:  Although we of course support all efforts to limit the uncontrolled spread of PFAS in the environment, we criticize that the proposed restriction does not differentiate between fluoropolymers (such as PVDF, ECTFE, FEP, PFA and PTFE as wells as fluoroelastomers - FPM, FFKM, ...) and other PFAS. We request: - the restriction proposal to differentiate between the various types of PFAS based of their chemical composition, their toxicological profile and the production method. Not all PFAS are the same and there is no scientific basis to regulate them all the same. - fluoropolymers to be exempted. Fluoropolymers use brings significant benefits along the value chain, making them essential in numerous technologies, industrial processes and everyday products. Their chemical inertness and resistance to harsh conditions, corrosion and extreme temperatures (hot and cold) are unique properties, required in a wide range of applications. Banning Fluoropolymers will make it impossible be successful with key initiatives of the European Union: the green deal, the sustainable development goals, energy transition and the European Chips Act. Most fluoropolymer-based products have been developed to support the EU concept of high safety in the chemical industry, e.g. in chlorine and sulfate production itself and in downstream intermediates such as MNB, TDI, MDI, VCM, HF, etc. The end products are used for all critical purposes, such as environmental protection: climate change mitigation/adaptation, circular economy, water supply sustainability, pollution prevention or biodiversity; human health: public health protection. Society, governments and the military are affected by the lack of the above products, resulting in missing products and significantly reducing global power. Any alternative polymer, which has an equivalent link to fluoropolymers, has to provide a same or better compound between the atoms. As a result, these alternatives are expected to show the same long-lasting behavior in the environment. |
| Answer to specific info request 1:  We are a 80 FTE manufacturer of pumps and pumps with inner coatings made from fluoropolymers (PTFE, PFA) and we are using seals and gaskets made from fluoropolymers (PTFE) and O-rings made from FKM or FFKM in our pumps made from ceramics or metal alloys. Our pumps and parts are used in industrial applications in all industries worldwide, especially in the chemical and pharmaceutical industries. In the chemical and pharmaceutical industries in particular, goods made from fluoropolymers are used in virtually every plant as flange seals for pipelines, in valves as valve body- and spindle seals and in pumps as gaskets or internal coatings to convey highly aggressive or ultra-pure gases or liquids to protect the environment for spills or to fluid itself for dilution. The corrosion resistance and high temperature suitability of fluoropolymers are the key factors for the use of fluoropolymers in these applications. The corrosion resistance of FP is based on the compound between carbon and fluorine, which is the strongest compound in organic chemistry. Other polymers do not achieve this corrosion resistance because their chemical compound is destroyed earlier. The used fluoropolymers are extremely expensive (much more expensive than any other polymers that might also be considered for such applications), but are not replaceable due to their unique characteristics. With a ban of fluoropolymers, we will lose our complete business, which will also affect a wide range of sub-suppliers even for parts not made from fluoropolymers (metal parts, ceramic parts, electric and electronic devices). Moreover, we cannot imagine how the chemical and pharmaceutical industries worldwide can meet their high safety and environmental standards without these components, which are essential for the tightness and safety and have been tried and tested for decades. We therefore expect not only an end for machine and plant manufacturers in Europe, but also a migration of end customers, i.e. the chemical and pharmaceutical industry, from Europe to Asia, South America and the U.S. Further details can be found in the attachment. |
| Answer to specific info request 2:  Our goods are used in industrial applications. During our manufacturing, when molding parts from PFA granulate, no waste occurs. Residuals are re-molded and re-used. When machining parts from solid sintered fluoropolymers (e.g. PTFE), we use sintered pre-forms to keep the waste as small as possible. This is done for cost reasons. Our residuals of sintered fluoropolymers are incinerated. Waste incineration above 800 °C ensures that all PFAS are destroyed. There will be no PFAS-emissions. At end-of-life phase, due to their contamination with chemical substances, our goods are collected and properly discharged. Again, waste incineration above 800 °C ensures that all PFAS are destroyed. There will be no PFAS-emissions. (Scientific report on waste incineration and thermal recycling: Chemosphere Volume 226, July 2019, Pages 898-906: Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Krasimir Aleksandrov; Hans-Joachim Gehrmann; Manuela Hauser; Hartmut Mätzing; Daniel Pigeon; Dieter Stapf; Manuela Wexler). Further details can be found in the attachment. |
| Answer to specific info request 3:  Our goods are used in industrial applications. At end-of-life phase, due to their contamination with chemical substances, our goods are collected and properly discharged. Waste incineration above 800 °C ensures that all PFAS are destroyed. There will be no PFAS-emissions. (Scientific report on waste incineration and thermal recycling: Chemosphere Volume 226, July 2019, Pages 898-906: Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Krasimir Aleksandrov; Hans-Joachim Gehrmann; Manuela Hauser; Hartmut Mätzing; Daniel Pigeon; Dieter Stapf; Manuela Wexler). Further details can be found in the attachment. |
| Answer to specific info request 4:  Case studies already proved recyclability of fluoropolymers (e.g. Dyneon Upcycling plant Burghausen Germany). |
| Answer to specific info request 6:  Further details can be found in the attachment. |

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| 4573 | Date:  2023/06/16 08:15  Content:  Scope or restriction option analysis  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  Please treat this as confidential material because it contains our product technical information, PFAS alternative study data, and confidential information regarding our market share. | General Comments:  PFASs are used in flat panel displays (FPDs). Since no alternative technology has been found at this time, a regulatory option with a grace period of 12 years is appropriate. We support the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV. |
| Answer to specific info request 1:  Materials for flat panel displays (FPDs) such as LCDs and OLEDs |
| Answer to specific info request 5:  Attached as confidential material in Section V. |
| Answer to specific info request 6:  Attached as confidential material in Section V. |

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| 4574 | Date:  2023/06/16 10:27  Content:  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Shenzhen Kedali Industry Co., Ltd.  Org. country:  China  Attachment:  <redacted>  Privacy statement:  There are some figures/ information related to Kedali's business secrets. | General Comments:  Restriction Background The proposed restrictions in the Annex XV restriction report includes many types of PFAS, and PFA is one of them. However, the restriction report doesn’t differentiate between PFA and other PFAS. PFA has unique properties that distinguish it from other PFAS.  No PFA Alternative PFA is mainly used for battery lids structure regarding the products produced by Kedali. PFA has excellent resistance to high and low temperature/electrolyte/acid and alkali, which makes it a perfect material for battery lids sealing parts. The battery lids are used for many different purposes, and their safety considerations are thus particularly important. The use of PFA in battery lids can not only meet the strict safety requirements but also provide necessary protection for the internal components of the battery. (Please refer to Advantages of PFA Lid Sealing Structure in “Section V. Confidential Attachment” - this is an analysis received from our supplier )  PFA performance in Battery Lids applications:  Thermal Stability: PFA is able to maintain its physical and chemical properties under high temperature conditions, which is important for battery lids because batteries may generate high temperatures during charging and discharging. Chemical Inertness: PFA is inert to many chemical substances, i.e. it is not easy to react chemically with other substances. Electrical Insulation: PFA is a good electrical insulation material, which can effectively isolate the current in the battery and reduce the risk of leakage and internal short circuit. Corrosion Resistance: PFA has good resistance to many chemicals such as acid, alkali and solvent, which makes PFA in battery lids able to withstand the acidic or alkaline environment generated in the battery and provide protection in the battery environment. Low Coefficient of Friction: PFA has a low coefficient of friction, which allows it to provide good sliding properties during battery assembly and disassembly, and thus to reducing frictional losses and wear.  Although there are other materials that can be used in battery lids, these materials still have some limitations compared to PFA. Some of the materials that may be used for battery lids, including PP, PPS, PEEK and FKM, perform better than PFA in some aspects, but they are not superior to PFA in other aspects.  PFA has also been proven to be a reliable and effective material for use in battery lids and is so relevant to people’s lives that it cannot be replaced. - (Please refer to The Necessity of PFAS (Perfluorinated and Polyfluoroalkyl Compounds) in Sealing Components in “Section V. Confidential Attachment” )  Low Hazard to Human Health According to Kedali’s understanding on PFAS Restriction Proposal, it is proposed because PFAS is considered to be extremely harmful to the environment and human health. However, PFA is generally considered to have low hazards to human health for the following reasons:  1. Low Absorption: PFA has low absorption rates in the human body, meaning that it is not easily taken up into the bloodstream after exposure. This characteristic reduces its potential to cause systemic toxicity. 2. Low Acute Toxicity: PFA has low acute toxicity, which means that it does not typically cause immediate harm or severe toxic effects when encountered in high concentrations. This characteristic contributes to its low hazard profile. 3. Stability: PFA is highly stable compounds, making it resistant to degradation in the environment and reducing the likelihood of immediate breakdown into more toxic substances. This stability also contributes to its low hazard potential. 4. Limited Bioaccumulation: While some PFA can accumulate in living organisms over time, the extent of bioaccumulation is generally low compared to other persistent organic pollutants. This limits its potential to reach harmful levels in the food chain and reduces the overall risk to human health. 5. Inertness: PFA is relatively inert substances, meaning it has low reactivity with biological systems. This inertness reduces the likelihood of direct interactions with cellular processes and reduces the potential for adverse health effects.  Request for Exemption We do not deny that there are many PFAS materials that are extremely harmful to the environment and even to human beings, and such materials should be banned. However, there is no alternative material for PFA and it has low hazard to human health. Therefore, we request for exemption for PFA. |
| Answer to specific info request 6:  For the battery lids produced in Kedali, there is no alternative for PFA. If PFA is banned, Kedali will no longer be able to produce any products containing PFA and export them to Europe, then all the production lines, equipment, toolings, fixtures, manpower, etc. that Kedali has previously invested by Kedali related to these products will lose their value, which will cause a great degree of socio-economic impact: If PFA is banned, Kedali will not be able to carry out the relevant production, which will result in the following losses in terms of production lines, equipment, tooling/fixtures, manpower, etc. : Expected losses for Kedali Global: 1) Losses of production lines and equipment are expected to be as high as [CONFIDENTIAL] RMB, or [CONFIDENTIAL] Euros. 2) Losses of toolings/fixtures, etc. are expected to be as high as [CONFIDENTIAL] RMB, or [CONFIDENTIAL] Euros. 3) Loss of manpower is expected to be as high as [CONFIDENTIAL] RMB, or [CONFIDENTIAL] Euros. Please refer to the Expected losses due to PFA restriction in “Section V. Confidential Attachment” for detailed figures. The above losses includes both the losses at home and abroad. There are several plants built in Germany, Hungary, Sweden, etc, by Kedali, and all the production lines and equipment, toolings/fixtures prepared in the European countries are based on the cooperated European customers’ actual demands on Battery lids and Cans. If PFA is banned, all the PFA-related products will not be able to produced and used, and both Kedali Europe and all its European customers will suffer a huge loss. As the PFAS Resitriction is proposed by Europe, Kedali thinks it is necessary to indicate the specific losses in Kedali Europe separatly. Expected losses for Kedali Europe: 1) Losses of production lines and equipment are expected to be as high as [CONFIDENTIAL] Euros. 2) Losses of toolings/fixtures, etc. are expected to be as high as [CONFIDENTIAL] Euros. 3) Loss of manpower is expected to be as high as [CONFIDENTIAL] Euros. Please refer to the Expected losses due to PFA restriction in “Section V. Confidential Attachment” for detailed figures. If Kedali is not able to carry out the relevant production, then many workers will face unemployment, which will have the following impact on society: Expected unemployment staff for Kedali Europe: 1)The number of unemployed staff abroad is expected to be as high as [CONFIDENTIAL] Please refer to the Expected losses due to PFA restriction in “Section V. Confidential Attachment” for detailed figures. Kedali and its customers have a long-term strategic cooperative relationship, which makes Localization a necessity for Kedali. In fact, Kedali is expected to build a few more plants in Europe to meet the customers’ demands. If PFA is banned, then 1) many current workers will face unemployment, as mentioned above; 2) it will be meaningless for Kedali and other companies to build more plants in Europe and employ more local workers, and less employment opportunities, without any doubt, will cause some negative impact on society. 3)Kedali will lose strategic opportunity for globalization. 2)An increase in unemployment can have various impacts on society. Here are some of the common effects: 1. Economic Impact: High unemployment rates can strain the overall economy. With fewer people earning income, there is a reduction in consumer spending, leading to decreased demand for goods and services. This, in turn, can negatively affect businesses, leading to lower profits, potential closures, and reduced investment. 2.Poverty and Income Inequality: Unemployment often leads to financial hardships, particularly for individuals and families who rely on a steady income. Increased unemployment can contribute to higher poverty rates and widen income inequality within society. 3.Social Unrest: A rise in unemployment can lead to social unrest and dissatisfaction, as individuals and communities may become frustrated with their economic circumstances and the perceived lack of opportunities. This unrest can manifest in various forms, including protests, civil unrest, and increased crime rates. 4.Government Finances: Increased unemployment places a burden on government finances. As unemployment rises, there may be an increased demand for social welfare programs, unemployment benefits, and other forms of public assistance. Governments may face challenges in managing these increased expenditures while balancing the budget. A large part of the battery lids produced by Kedali is exported to Europe, and the annual sales in Europe is about [CONFIDENTIAL] Euros. If PFA is banned and the related products cannot be exported to Europe, it will have an equally large social and economic impact on related industries in Europe. Please refer to the Expected losses due to PFA restriction in “Section V. Confidential Attachment” for detailed figures. |
| Answer to specific info request 7:  For PFA, there are no technically and economically feasible alternatives at this stage, nor are there any alternative-based products available on the market. Therefore, if PFA is banned, there will be no possibility to be exempted from a series of social and economic impacts caused by PFA ban. |
| Answer to specific info request 8:  See the answer in Comments for Specific Information Request No. 6 for details. |

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| 4575 | Date:  2023/06/16 10:56  Content:  Hazard or exposure  Environmental emissions  Description of analytical methods  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Switzerland  Company name confidential:  Yes  Attachment:    <redacted> | General Comments:  Our company is an international group active in the design, manufacture, and sale of finished watches, jewelry, watch movements, and components. Our group supplies nearly all components required by its watch brands which in turn supply watch movements (i.e. the mechanism of a watch) and components to third-party watchmakers in Switzerland and around the world. One company of the group is specialized in the production and commercialization of lubricants and epilames, used primarily for watchmaking applications. This company is supplying the watch brands as well as third-party watch manufacturers. Our company values the opportunity to submit comments regarding the proposed restriction of PFAS under the REACH Regulation. With this contribution, we would like to express our concerns regarding the absence of derogations for the manufacture and use of the so-called “epilame” and “epilame mixtures” for the lubrication process of internal watch movement parts. Epilame mixtures are manufactured using fluorinated polymers (epilame), considered as PFHxA-related substances in the context of the restriction proposal on PFHxA, and a fluorinated gas-based carrier fluid, which falls under the scope of the currently proposed PFAS definition. To note, a derogation request for the epilame (fluorinated polymers) was submitted during the consultation phase of the restriction proposal on PFHxA. This derogation was included in the restriction proposal by the Dossier Submitter, and supported by the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC). Despite this, the PFAS restriction proposal proposes to ban the placing on the market and use of epilame mixtures and watches containing epilames 18 months after entry into force. As the epilame coating is required to ensure the proper lubrication of the mechanical parts of watches, the ban will make it virtually impossible to ensure the proper manufacturing of watches, as well as the servicing of watches currently used by consumers. Our company is continuously evaluating and looking for alternatives to its materials from both an environmental and cost perspective. To date, no alternative materials have been identified that can replace PFAS on performance/functionality and that would be less harmful to the environment. In the context of the PFAS restriction proposal, we want to request the following permanent derogation: 5. By way of derogation, paragraphs 1 and 2 shall not apply to: xx. epilame used in watches; xx. epilame mixtures used in watch manufacturing and servicing; xx. recycled fluorinated gases making use of a derogation according to paragraph 5 xx) [epilame mixtures used in watch manufacturing and servicing]; |
| Answer to specific info request 1:  This contribution applies to the following use sectors: lubricants (sector as a whole) and applications of fluorinated gases (solvents). More specifically, it addresses the use of PFAS, including fluorinated polymers (lubricant sector) and fluorinated-based carrier fluids (solvent sector), for the manufacture of epilame mixtures to be used as a part of the lubrication process for internal watch movement parts in mechanical and quartz watches. |
| Answer to specific info request 2:  Regarding question 2.a, please refer to Question 6(a). Regarding question 2.b: All wastes from production are collected and properly incinerated. Where we operate, special waste treatment companies are authorized by national authorities to collect the waste of fluorinated compounds. Subsequently, these substances are subject to high-temperature incineration. In the last decade, a growing demand for recycling epilame mixtures has been observed. End users having large volumes of expensive epilame mixtures are increasingly asking for cost effective recycling solutions instead of destruction. |
| Answer to specific info request 3:  See our answer to question 6.a.ii of our confidential version. |
| Answer to specific info request 4:  Regarding question 4.a: As explained under Question 2(b), there is an increasing trend to recycle the fluorinated gas-based carrier fluid from used epilame mixtures. This allows to reduce the manufacture of new fluorinated gases for the production of epilame mixtures and is in line with the overall objective of the restriction. The concentration limits proposed in paragraph 2 of the proposed restriction entry text would impede the recycling of fluorinated gas-based carrier fluids. We believe that for derogated uses, it should be possible to allow recycling of PFAS such as fluorinated gases. This should apply to fluorinated gases used in epilame mixtures. Regarding question 4.b: Not relevant, as it would not be possible to achieve the proposed concentration limits. Regarding question 4.c: Not relevant, as it would not be possible to achieve the proposed concentration limits. |
| Answer to specific info request 5:  Our use is a missing use developed under question 6. |
| Answer to specific info request 6:  Regarding question 6.a: i. Production of epilame and epilame mixtures Production of epilame and epilame mixtures takes place at laboratory scale worldwide. Waste is collected as industrial chemical waste and is properly treated through high-temperature incineration. ii. Use of epilame mixtures The epilame mixtures are sold to end users (i.e., watch industries and watchmakers) for industrial and professional uses only. These mixtures are not accessible to consumers through retail outlets. The annual tonnage of epilame mixtures used in EU (including Switzerland) could be estimated to approximately 8 tonnes (mainly F-Gas as carrier fluid). This tonnage is rather small (c.a. 0.002%) in comparison with the annual tonnage of F-Gas used in EU. Considering the large variety of industrial equipment and processes from one user to another, it is not possible to have a precise estimation of the total emissions of PFAS during the entire watchmaking process. Based on our experience, considering that 90% of the volumes of used mixtures are collected and properly disposed, and considering the modern equipment (equipped with activated carbon collecting approx. 9%) used at industrial sites, we can reasonably assume that the estimated release to the environment is approximately 1%, below 100 kg/year. During the service of a watch, the watch is opened, and some parts of the movement are removed and examined. It is mandatory to clean some of the epilame-containing pieces of the movement and renew the lubrication. The chemical waste resulting from this process is collected and properly disposed of. For more detailed information concerning tonnage and potential release in the environment, please refer to our confidential contribution. iii. Use of the watches The carrier fluid (fluorinated gas) is not present on watch pieces. Only the epilame (fluorinated polymer) is coated on top of internal watch movement pieces. Watches only contain a small amount of epilame (< 0.1 kg/year on a global scale). No releases of epilame coated onto all the watch parts can happen under normal conditions of use, as watch movement parts are contained in the hermetic water resistant watch case and are not accessible to the user nor the environment. iv. End of life of watches The large majority of watches produced are reused or recycled in a way depending on their type. Three different scenarios happen depending on the watch type: i. Mechanical watches have a very long lifetime, sometimes even exceeding human lifetime, passing from one generation to generation. Moreover, mechanical watches are expensive products and are not disposed of as domestic waste. ii. Electronic watches containing a quartz movement (analogue watches) fall under the EU RoHS Directive 2011/65/EU and therefore are appropriately collected and eliminated as every waste of electronic device. Regarding question 6.b: i. Key properties of epilame (fluorinated polymers) The specific properties that are required for an efficient epilame are the following: 1. A low surface tension; 2. A chemical compatibility with all sorts of coated substrates as well as all lubricants used; 3. Ultrathin and transparent coating. ii. Key properties of carrier fluid (fluorinated gas) The carrier fluid used to solubilize the epilame polymer needs to fulfil the following requirements: 1. Compatibility with the epilame; 2. Good wettability resulting from a low surface tension and viscosity; 3. Fast drying and non-flammability; 4. Low Global Warming Potential (GWP) and low toxicity. Regarding question 6.c: As already mentioned, the epilame process is mandatory to ensure the proper lubrication of a watch movement. Without epilame a watch does not work properly. Therefore, as far as we know, we assume that all companies involve in this sector, watch-making industry, will be concerned. Regarding question 6.d: As indicated in the RAC and SEAC Opinion on PFHxA, silicone-based coatings have been investigated as potential alternatives, but they do not meet the technical requirements. In addition, stearic acid, which was used for epilamisation decades ago, does not fulfil current industry standards due to its poor oil repellence and its weak wash resistance. For further information, please refer to our confidential contribution. Regarding question 6.e: Please refer to our confidential contribution. Regarding question 6.f: Not relevant, as there are no alternatives available. Regarding question 6.g: i. Impact on consumers The lubrication of watches, especially mechanical watches, is a very complex and delicate process requiring several steps. A classical watch movement may require more than 60 lubrication steps, using many different products at specific locations. Without an epilame to maintain the lubricant into the contact, a watch can stop within weeks or even days. Even though it is difficult to predict which function in the movement may fail first due the lubricant starvation, multiple failures will occur and the watch will rapidly stop working. Moreover, servicing of watches already on the market will not be possible. As a result, customer services will not be able to oil watch movement parts, leading to the early obsolescence of watches. ii. Impact on the watch industry: Altogether, the restriction under consideration, without derogation, could put at risk between 167,000 and 188,000 jobs and potentially lead to €3.0 billion in loss of export revenues and €1.3 billion in loss of tax incomes and social security contributions. Considering the small quantity of fluorinated polymer substances annually placed on the market and the proper waste collection and high-temperature incineration by specialised treatment centres, we can conclude that the socio-economic implications of not granting a derogation for the watch industry are largely disproportionate. iii. Annual value of EU sales and profits of the relevant sector In 2020, watches generated €2.44 billion in export revenues for the EU, despite the significant impact of the Covid crisis (-19.6% compared to 2019). In addition, €536 million of EU watch components and straps were exported to Switzerland in 2020. Furthermore, according to these figures, the taxes generated in the EU by the analogue watchmaking industry could be estimated as follow: €780 million for VAT, €210 million for direct and indirect taxes on household income, and €70 million for direct and indirect corporate taxes. In addition, the analogue watchmaking industry contribution to social security is estimated at €230 million. iv. Employment numbers for the sector In 2020, the watchmaking industry, jewellery industries and downstream sectors employed 167,000 workers in the EU, including production, aftersales services and product distribution. In Switzerland, around 61,000 workers are employed in the watch production (including 21,000 cross-border workers, mainly from France, Germany, and Italy). |
| Answer to specific info request 7:  Our exemption request is a new one, not for reconsideration. |
| Answer to specific info request 8:  Our use is a missing use developed under question 6. |
| Answer to specific info request 10:  We are not aware of any analytical methods available to enforce the proposed restriction with regard to internal watch parts. In the context of the PFHxA restriction proposal, the Enforcement Forum already highlighted the absence of applicable analytical methods addressing precursor compounds (e.g., fluorinated polymers). This upcoming restriction could, therefore, jeopardise the production of epilames and watches in Europe while not being able to control imported watches. |

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| 4576 | Date:  2023/06/16 11:08  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  Analysis of Scope or Limitation Options The proposed restriction makes no distinction between polymeric PFAS and other PFAS, but there is no basis for polymeric PFAS to be regulated. Although the persistence of PFAS is cited as the reason for the restriction, it cannot be said that polymers other than plant-derived or biodegradable plastics also degrade completely in nature. What is the rationale for the polymeric PFAS in particular to remain in the environment longer than other polymers? Hazard or exposure In products made with polymeric PFAS, polymeric PFAS exists in a stable state. There is a low risk that particulates of polymeric PFAS will spread or seep into liquids and cause marine pollution. Information on Alternatives Polymeric PFAS has characteristics not found in other polymers, and therefore, we believe that it is irreplaceable. It may be substitutable in terms of only some functions, but in terms of comprehensive functions, it is not a substitute but a degradation. |
| Answer to specific info request 1:  Electronics and semiconductors, Electronics |
| Answer to specific info request 8:  Fluoropolymers (FEP, PFA, ETFE) and fluoro rubbers (TFE-PP, VDF-HFP) are widely used as sheathing materials for industrial cables used in ships, trains, large machinery, motors, and ironworks wiring, as well as for cables and wire harnesses to control electronic devices mounted in vehicles. These materials are required to have high heat resistance, high flame resistance, flexibility, oil resistance, abrasion resistance, and electrical insulation properties. None of the substitutes listed in Table 8 in the Annex XV report has sufficient properties to replace fluoropolymers or fluoroelastomers. For example, EPDM lacks heat resistance and oil resistance, and silicone rubber has insufficient tensile strength, heat resistance, and oil resistance. Other alternatives are listed in Table 1 and 2 in the attachment as a non-confidential document. Attached Table 1 shows the required properties of cables for various applications. Table 2 shows a comparison of the properties of fluoroelastomers and other alternative materials. The areas marked in red in Table 2 have low properties compared with fluoroelastomers, and which means that the requirements in Table 1 cannot be met. Currently, there are no materials that are sufficient to replace fluoropolymers or fluoroelastomers, and it is unlikely that materials that satisfy these performance requirements will appear on the market within the 18-month transition period. Furthermore, even with a 12-year grace period, it is very difficult. If this restriction is implemented, it will cause extremely serious damage to the supply of infrastructure facilities where ships, trains, and other transportation equipment and large machinery are used. In addition, the shift to EVs and FCVs will also be greatly affected, and there is an extremely large risk of a major impact on the reduction of carbon dioxide emissions. Furthermore, even if substitutes for fluoropolymers and fluororubbers were developed, even with the 18-month transition period and 12-year grace period, a stable supply would be extremely difficult , and the impact on society would be extremely large. |

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| 4577 | Date:  2023/06/16 11:09  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Nissan Motor Co.,Ltd.  Org. country:  Japan  Attachment: | General Comments:  1) About PFAS and PFAS regulations • The PFAS regulation is proposed to regulate chemical compounds through a grouping procedure already adopted for other fluorochemicals such as PFOA and PFOS. • However, Nissan believes that the proposed restrictions cover a much broader group of chemicals (thousands of substances) and that there has not been a proper scientific hazard and risk assessment of each substance or group of substances. • In the case of materials like PFAS, it should be recognized that the inherent property of persistence provides desirable properties of high durability and unique functionality to products manufactured and treated with this chemistry. • For example, electrical equipment is used in a variety of potentially harsh conditions and must function perfectly under those conditions. To maintain this high level of reliability and performance, components must be moisture, water and rust resistant, and withstand corrosion and extreme temperatures. • In order to meet the above requirements, functions such as low dielectric constant, low dielectric loss tangent, low refractive index, and oil repellency are essential. • Only PFAS materials can provide all the required functions and performance simultaneously in one material. • Currently there is no alternative to show the combination of all the above properties. • A recent review stated that '16 unique families of commercially popular fluoropolymers meet OECD criteria'. The abstract reads: Fluoropolymers are irreplaceable in many applications due to their unique combination of properties and unrivaled functional performance that are important to the products and manufacturing processes they enable. • A safety profile has been documented for fluoropolymers. They are thermally, biologically and chemically stable, practically insoluble in water, non-migratory, non-bioavailable, non-bioaccumulative and non-toxic. •Fluoropolymers fit the structural definition of PFAS, but have significantly different physical, chemical, environmental and toxicological properties when compared to other PFASs. • Large molecules, such as polymers, are continuous and nothing can penetrate into the cell membrane. Polymeric PFAS should be reconsidered as out of scope.  2) Global impact on auto parts • PFAS have been widely used in industry due to their unique properties: Very high stability, high temperature and high pressure resistance, electrical insulation, chemical resistance • Fluororesins and fluoroelastomers are both classified as PFAS and will be prohibited by this proposal, but by using them as coating agents, friction between materials can be reduced. This characteristic is very important for the automotive industry.  • F-gas is also widely used as a refrigerant in the automotive industry, and currently the main gas used in mobile air conditioners is R-1234yf. For further details, please refer to the views of the Japan Automobile Manufacturers Association and the European Automobile Manufacturers Association. • Please note that Nissan, as a downstream user, will be greatly affected by the following sub-use bans. - Lubricant - Application of fluororesin to batteries and fuel cells - About the use of PFAS in electronics and semiconductors - Fibers and fabrics used in automobiles  • As vehicle OEM is not the direct manufacturer of such goods or products above, Nissan shares relevant data collected on this subject. • The committee should refer to relevant submissions from professional associations to gain a clear understanding of the issues in a global perspective. • Nissan attached the investigation result for each item to clarify Nissan's position and provids them in the end of this document.  3) Maturity of alternative products • In the automobile industry, consideration of alternatives for some PFASs has progressed, but sufficient progress has not been made in examining alternatives for all PFASs. • Due to many of the properties that can be obtained from the use of PFAS, other alternatives for obtaining the same properties may influence the design of these applications themselves, making their validation and implementation more complex. • Finding alternative materials requires evaluating many parameters of candidate materials. Such an evaluation is a complex process, as a car is a highly complex product with thousands of parts and likewise dozens of different operating conditions. • This evaluation includes physical testing of the product for durability, temperature, humidity, crashes, and more. This test is time-consuming and can be expensive (several million euros per substance). • Therefore, it seems an unrealistic expectation for industry to systematically evaluate all possible substitutes for restricted PFASs in order to conclude the need for deregulation. • In general, such assessments should be focused on the specific use of the substance. In this case, the problem is that the use of PFAS in industry is still poorly informed, as stated in the Annex XV document. And a suitable replacement should be available: a. Be in sufficient quantity; b. Be of acceptable quality; c. Have the same performance and functionality (meet OEM-specific requirements that may vary by OEM) d. Consistent delivery over the life of the contract between supplier and OEM e. Comparable to the original material in terms of cost • Also Nissan must avoid substituting the materials that are less safe, sustainable and durable. by applying essential use definitions. • Such substitutions may result in trade-offs in long-term reliability, safety and emissions performance, or compromise the long-term sustainability of automotive products. •The default transition period should be at least 48 months or more to ensure a sufficient transition period, considering the given complexity and impact of the current proposed restrictions on multiple industry value chains, this is not realistic. •For reference, ECHA proposed a transition period of 36 months in its proposed limits for PFHxA and its salts. •Given the much broader scope of the proposed PFAS restriction, Nissan considers the 48-month transition period is to be a strict minimum for the industry to adapt its products and ensure compliance with the restriction.  4) Necessity to set the timing for reviewing the exemption period • Nissan requests a mechanism to allow further extensions to be applied for before the exemption period expires. • The industry wants to make every effort to find alternatives and develop alternative technologies for substances with demonstrated unacceptable risks. However, as noted above, fluorine-free alternatives are not always available and even safer. The reality is that there are applications for which there are no prospect of replacement. • It may not be possible to develop a suitable replacement before the extended transition period fixed for a particular exemption expires. Nissan therefore asks the authorities to consider introducing a review system similar to that currently in place for exemptions from the RoHS and ELV Directives.  5) Maintenance and Sustainability • The proposed regulatory states that general regulation of PFAS will come into force around 2026/2027, with the potential benefit of short-term and long-term exemptions for certain uses. • Nissan’s current understanding is that only a few automotive applications will benefit from the exemption under this draft, and the majority of automotive applications will, following issuance of this proposed restriction, Nissan has to redevelop, validate and implement on all models in production. • Furthermore, the maintenance of vehicles whose production will end in 2026/2027 will no longer be possible with spare parts according to the current definition, for example with the current air conditioning fluid (R1234yf). • Products placed on the market require the same spare parts that were originally used in the original product. Redesigning spare parts often requires redesigning the entire product. Otherwise, the original performance (that is, safety and durability) cannot be guaranteed. Given the supply chains and production processes of many manufacturers, such a redesign is almost never possible. • Maintenance and repair are key points in a vehicle's long life cycle. As past consultations have shown, phasing out substances in legacy spare parts is neither economically nor technically feasible. This issue was originally raised and resolved during the discussion and implementation of the EU's End of Life Vehicles (ELV) Directive (2000/53/EC). • The exemption of these spare parts under the ELV Directive has been confirmed by the Member States and the EU Commission (“repaired as produced”). This decision allows transport vehicles to be serviced, repaired and maintained in a manner that does not impair their function, safety and reliability, without limiting the types or categories of components. • The absence of exemptions for spare parts of any kind would seriously undermine the supply of spare parts and prevent vehicles from being serviced, repaired and maintained, strongly contradicting the overall strategic goal of a circular economy. • As such, Nissan supports mitigation measures that enhance the sustainability of its existing fleet in order to promote a 'repaired as produced' policy.  6) Regarding the traceability of PFAS in the supply chain •It is highly unlikely that the auto industry will be able to manage global PFAS regulations with the current proposals. The identification of PFAS is still in progress and it will likely take many years for the entire supply chain to provide relevant information. • Therefore, the time schedule of 18 months from entry into force is too short and most industries will not be able to meet it. •This is likely even considering that the auto industry already has tracking tools and strong databases to identify substances. But many suppliers and other industry sectors do not have access to the extensive tools that the automotive industry has. •Therefore, in this proposal, the time schedule to make the whole exemption period longer should be reconsidered. • The concentration limits set out in the Annex XV dossier are due to the lack of testing standards for fluorinated substances and the lack of a legal obligation for international supply chains to communicate PFAS content in parts and materials. Need to considers that the limit value cannot be applied under the present circumstances. • Although there are thousands of PFAS substances, currently only about 40 types of PFAS are registered in the database of the automobile industry. • The only thing Nissan can actually do is to ask each supplier about the actual usage situation, and support the schedule, cost, and quality confirmation plan regarding the possibility of substitution and switching in case of substitution. •For each item that Nissan believes requires an exemption, Nissan has provided relevant information and stated them at the end of this document. •Nissan has not finished investigating seal applications, lubricating oil applications, lubricants, electronic component applications, and heat-resistant harnesses at present. Further investigation will take more time. Iit is estimated that there will be cases which would be difficult to substitute for applications that Nissan has not been able to grasp so far, when Nissan asks suppliers to switch in the future. •Nissan would like to clarify as much as possible and submit additional information by the comment deadline in September. |
| Answer to specific info request 6:  1) Semiconductor manufacturing process [Current state of use] It has been found that PFAS are being used in the following manufacturing processes of semiconductors:  Etching process (1) C4H8, CH2F2 and other PFAS are used as etching gas (in formation of microcircuits) (2) Used in cooling refrigerant to keep wafer temperature down (precision temperature control)  Equipment materials (1) Used in high-quality fluorine rubber in the product form of vacuum sealants (highly clean, heat resistant, plasma resistant) (2) Used in fluororesins in the product form of chemical tubes, joints, valves [Possibility of substitution / Time needed for substitution] Reportedly, at present there are no means of replacing the PFAS used in the manufacture of high-performance semiconductors. A grace time is definitely necessary to develop substitute technologies for these PFAS, or automobile production will become impossible. While Nissan cannot state exactly when such substitute technologies will be completed, our best projection is a minimum grace requirement of 13.5 years. According to the explanations given by experts, the PFAS used in the semiconductor manufacturing process do not infiltrate into any automotive product. 2) Lithium-ion batteries [Current state of use] Indispensable for lithium-ion batteries, fluorine-based materials are used in these batteries in large amounts. Examples of use are as follows:  Separator The separator is the porous material that transmits lithium ions across itself and is placed between the positive and negative electrodes in order to prevent their direct contact and thus their internal short-circuiting. For realizing its above-mentioned function, the separator must be made electrically insulated and ion-conducting. For its stable operation, the lithium-ion battery requires a chemical stability (e.g. electrolyte resistance, humidity resistance), an electrochemical stability (e.g. reduction resistance against negative electrode, oxidation resistance against positive electrode), and a mechanical strength. Furthermore, for the safety of the lithium-ion battery as a whole product, a shut-down function and a heat-resistant characteristic are required. To satisfy these requirements, PFAS such as polyvinylidene fluoride (PVDF: CAS 24937-79-9) are applied to the separator as a coating fluororesin.  Binder An electrode active material adjoining with aggregates (e.g. metal foil) or with electrolytes, the binder comes in a powder body. In many cases, a binding or bonding agent is used to maintain a layer of electrode active materials adjoining with themselves or with aggregates, etc. The electrode binder is required to have properties such as chemical stability, electrochemical stability, high adhesiveness (peel strength), and minimum increase in internal resistance. Most representative of organic solvent binders is the crystalline thermoplastic PVDF which boasts a marked mechanical strength and excellent workability. Also highly chemical/heat resistant, PVDF is in wide use as binder for positive electrode. [Possibility of substitution / Time needed for substitution] Despite the passage of 30 years since the successful development of lithium-ion batteries, Nissan still lacks materials that can substitute for PVDF used in lithium-ion batteries. PVDF is also used in non-lithium-ion batteries such as ASSB and Na batteries. According to the product development roadmaps drawn by battery suppliers, batteries that use PVDF will continue to be the mainstay until around 2035. Consequently, it would be reasonable to estimate a requirement of 10 years for the development of a substitute material, another 10 years for the validation of PFAS-free batteries, and an additional 10 years for the practical application of these batteries to vehicles--amounting to a total grace period of 30 years. We, Nissan, would therefore seek an indefinite grace period initially; then review the grace period at the 10 year after entry into force (EiF). 3) Coating and finishing 3) -1 Surface coating [Current state of use] PFAS are used in the surface coating of parts and components. As mentioned early, Nissan is downstream users of PFAS. As such, Nissan is asking our business partners for possible shift to substitute materials, while our survey on the impacts of PFAS restriction is still underway. Nissan is proud to say that Nissan models live up to the high technological levels demanded in the European safety and environmental regulations. At the same time it is true that each one of the parts and component comprising vehicle, if its material is altered, can have significant impacts on the required safety and environmental levels. To identify these potential impacts, a large number of tests and a long period of time are required. As for other actual conditions, Nissan believes that the same consideration, as the plating solution described below, is necessary for electroless nickel phosphor plating and flake baking coating (Geomet treatment) ,they are under investigation though. - Topcoats of electroless nickel phosphorous plating contain PTFE for a different reason than in chrome plating, and which use of PTFE is essential. There is information that some plating solution companies are preparing PFAS-free products, Nissan believes that it is necessary to secure a sufficient supply volume in the plating solution market and ensure a sufficient period of time for upstream suppliers to supply plating products that meet the quality requirements of automobile OEMs. Zinc flake baking coating (Geomet treatment), which is widely used for automobile parts, involves immersing parts in a treatment solution containing zinc flakes and baking them to form a strong coating film. At the moment, Nissan has not received any reply from the supplier that it is possible to replace it, and the number of adopted parts per vehicle is enormous. When setting exemption deadlines, consideration should be given to sufficient time to allow supply chains to switch. 3)-2 Plating solutions (chrome/general plating) Nissan is aware that for hard chrome plating a grace of 6.5 years (1.5 year from publication to implementation + 5 years) has been proposed. 5o. [hard chrome plating until 6.5 years after EiF] In addition to the above-mentioned 6.5 years, Nissan as OEM sees a need for at least 3 years of grace for access to a satisfactory plating solution, for the plating supplier’s compliance testing on plated products, for the OEM’s quality check on anti-rust durability and fastening power, and for the normal procedure on vehicle type approval. (Adding the period requested by the Japan electro-plating industry association, Nissan believes the proposed grace of 6.5 years should be extended to around 10 years.) [Details] Assuming that a plated product has proved its required performance: ‒ 1 year needed for the plating supplier’s product assessment + Check on the product’s anti-salt/anti-rust durability and fastening power (e.g. axial force) ‒ 2 years needed for OEM’s check on the part/component performance and on the assembly work procedure involved ‒ A minimum total of 3 years is needed 4) Position on Safety Polymers [Scope of safety] In the Annex 15 report, the following applications are subject to reconsideration of potential derogation: 6o. [applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF] Regarding the “safety of transport vehicles”, Nissan considers it more appropriate to alter the above definition to “safety of all the parts and components of transport vehicles”. The reasons for the recommended alteration are: 1) Automobiles (four/two-wheeled vehicles) themselves are products for which a high level of safety is demanded. 2) To ensure the safety of automobiles, all their parts and components must function properly and continuingly throughout their lifecycle. Rather than limiting the scope to “proper functioning” and “the safety of operators, passengers and goods” in Annex 15, it would be more appropriate to include all the parts and components of the automobile in the scope. The following parts and components are particularly important for safety, and Nissan would like to provide information on them in the subsequent sections. If Nissan obtains more information in the weeks ahead, Nissan may submit an additional report. ‒ Surface coating ‒ Airbags, seatbelts and other safety-related devices ‒ Brake pads, wipers ‒ Wheel weight affixing tapes 5) Fuel/intake piping systems [Current state of use] The fuel piping system has many requirements to be fulfilled, such as heat resistance, chemical resistance, physical flexibility, low fuel permeability from the pipe surfaces, low friction characteristics for static electricity suppression, and low elution of fuel from the pipe surfaces. In response to these requirements, there are many kinds of materials or structures of the hoses used in the fuel piping system and have been developped. For example, NBR/PVC single-layer rubber hoses to 2-layer rubber hoses with FKM (fluororubber) as a barrier layer, or A resin/rubber composite type in which a thin film resin of PVDF (polyvinylidene fluoride) is attached to the inner surface of the hose, and furthermore, ETFE (ethylene-tetrafluoroethylene copolymer) and PA12 (polyamide 12) resin corrugated type, as well as GECO (epichlorohydrin rubber), CSM (Chlorosulfonated polyethylene), and POM (polyacetal resin) etc. For the similar purpose, FKM is widely used for the O-rings to connect and seal of UREA SCR (Selective Catalytic Reduction) system, in order to purify the diesel exhaust emission (i.e. NOx). The intake hose for the connecting the turbo and intercooler is exposed to mixed high temperature air compressed by the turbo and the EGR oil mist (blow-by gas). So, FKM is used in the ICE intake piping (hose, tube) system and the back pressure sensor hose for diesel engines, which require both heat and oil resistant properties. PTFE (polytetrafluoroethylene) is also applied for hoses in the air conditioner piping which require heat resistance, chemical resistance, flexibility, and low permeability properties. [Possibility of substitution] Presently there are no alternative materials to satisfy the above-mentioned characteristics. [Time needed for substitution] Assuming that a promising substitute material has been found, its actual performance must be validated in part/component state and in vehicle state. Consequently, 10 years will be required from the finding of the substitute material. [Necessary grace period] Although a period of 13.5 years from EiF has been proposed, Nissan wish to recommend extension of the proposed exemption to an indefinite period of time since a suitable substitute material has not yet been found. This indefinite period can be reviewed at the 10th year from EiF. 6) Membranes [Current state of use] PTFE membrane filters are used in great many types of parts/components to prevent the infiltration of liquids (e.g. water, oil) and contaminants (e.g. dust) while maintaining the pressure inside the equipment. Typical parts/components of these filters include various control units (e.g., engine control unit), lamps (e.g. headlamp, rear lamp, fog lamp), batteries, sensors (e.g. humidity sensor, air sensor, tyre air pressure monitoring system), drive controllers, inverters, converters, millimeter wave radars, and onboard cameras. As their common characteristic, these parts and components require a certain level of breathability so that their sealed areas will not be damaged through repeated internal/external pressure gaps caused by changes in temperature and altitude during driving. From the damaged sealed site rainwater and dust infiltrate into the part, causing malfunction and impairing safety. On the other hand, the use of non-fluorine filters would alter their surface condition in the long term through the effect of water, oil, dust. This would cause clogging and water intrusion, thus ruining the required durability of the automobile. [Possibility of substitution / Time needed for substitution] Since no substitute technology exists at present, it is not possible to estimate the length of necessary grace time. |

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| 4578 | Date:  2023/06/16 11:12  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  Analysis of Scope or Limitation Options The proposed restriction makes no distinction between polymeric PFAS and other PFAS, but there is no basis for polymeric PFAS to be regulated. Although the persistence of PFAS is cited as the reason for the restriction, it cannot be said that polymers other than plant-derived or biodegradable plastics also degrade completely in nature. What is the rationale for the polymeric PFAS in particular to remain in the environment longer than other polymers? Hazard or exposure In products made with polymeric PFAS, polymeric PFAS exists in a stable state. There is a low risk that particulates of polymeric PFAS will spread or seep into liquids and cause marine pollution. Information on Alternatives Polymeric PFAS has characteristics not found in other polymers, and therefore, we believe that it is irreplaceable. It may be substitutable in terms of only some functions, but in terms of comprehensive functions, it is not a substitute but a degradation. |
| Answer to specific info request 1:  Electronics and semiconductors, Electronics |
| Answer to specific info request 8:  Fluoropolymer tapes (FEP tape, PFA tape, and ETFE tape) are often used as interconnections, hold-down wraps, and separators in the process which make wires and power cables used in ships, trains, large machinery, motors, ironworks wiring, semiconductor plant delivery equipment, transportation equipment, and automobiles. The primary requirements for these tapes are slipperiness (contact angle), heat resistance, flexibility, oil resistance, and strength. In addition, low dielectric constant is required when used for telecommunications applications. None of the alternatives listed in Table 8 in the Annex XV report have sufficient properties for fluoropolymers. For example, EPDM is completely inadequate in terms of slip and heat resistance, and silicone rubber is inadequate in terms of slip, strength, and oil resistance. Other alternatives, such as cross-linked polyethylene, polyethylene, and PVC, do not have heat resistance above 125°C and their slipping properties are also unsatisfactory. The tape made of PEEK shown in the example can not roll the base because of low flexibility. Other polyamide resins and polyesters also cannot be used because not only low heat resistance and slipperiness, but also high hydrolysis which cause life span-decreasing of cable. Thus, at present, there are no materials that are sufficient to replace fluororesin or fluoroelastomer, and it is unlikely that materials that satisfy these performance requirements will appear on the market within the 18-month transition period. Furthermore, even with a 12-year grace period, it is very difficult. If these restrictions are implemented, it would be extremely damaging to the supply of ships, trains, and other transportation equipment, as well as to the supply of infrastructure facilities where large machinery is used, semiconductor manufacturing, and transportation equipment. Even if substitutes for these fluoropolymers are developed, even with the 18-month transition period and 12-year grace period, it will be extremely difficult to ensure a stable supply, and the impact on society will be extremely large. |

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| 4579 | Date:  2023/06/16 11:16  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  Analysis of Scope or Limitation Options The proposed restriction makes no distinction between polymeric PFAS and other PFAS, but there is no basis for polymeric PFAS to be regulated. Although the persistence of PFAS is cited as the reason for the restriction, it cannot be said that polymers other than plant-derived or biodegradable plastics also degrade completely in nature. What is the rationale for the polymeric PFAS in particular to remain in the environment longer than other polymers? Hazard or exposure In products made with polymeric PFAS, polymeric PFAS exists in a stable state. There is a low risk that particulates of polymeric PFAS will spread or seep into liquids and cause marine pollution. Information on Alternatives Polymeric PFAS has characteristics not found in other polymers, and therefore, we believe that it is irreplaceable. It may be substitutable in terms of only some functions, but in terms of comprehensive functions, it is not a substitute but a degradation. |
| Answer to specific info request 1:  Electronics and semiconductors, Electronics |
| Answer to specific info request 8:  Fluoropolymers (FEP, PFA, ETFE) are often used as coating materials for wires and cables used in semiconductor factory delivery equipment, delivery transmission cables, and sensor wires such as fire detection lines and temperature detection lines. The coating materials used in these products are required to have slipperiness and dielectric constant as the first requirement, and heat resistance, strength, and flexibility as the second requirement. However, there is no resin that can satisfy the dielectric constant and slipperiness of these fluoropolymers and has even higher heat resistance, so there is no substitute for them. The alternatives shown in Table 8 in the Annex XV report all have insufficient properties for fluoropolymers. For example, EPDM and silicone rubber are not satisfactory at all in terms of slipperiness and dielectric constant. As for other alternatives like cross-linked polyethylene, polyethylene, and PVC, dielectric constant and slipperiness are also not satisfactory, and heat resistance of these materials is below 125°C which is not compatible at all. The PEEK shown in the example has sufficient heat resistance, but can not be used because dielectric constant and flexibility do not meet. Polyamide and polyester can not be used because of their high dielectric constant, and their low slipperiness and heat resistance. In addition, since these material have high hydrolyzable, the product life of the cables is greatly reduced, so they can not be used. Thus, at present, there are no materials that can replace fluororesin or fluororubber, and it is unlikely that materials that satisfy these performance requirements will appear on the market within the 18-month transition period. Furthermore, even with a 12-year grace period, it is very difficult. If these restrictions are implemented, it would be extremely damaging to semiconductor manufacturing, logistics, disaster prevention, and power supply (used as sensors). The impact on the industry would be very large. Furthermore, even if alternatives to these fluoropolymers were developed, even with this 18-month transition period and a 12-year grace period, a stable supply would be extremely difficult, and the impact on society would be extremely large. |

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| 4580 | Date:  2023/06/16 11:19  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  Analysis of Scope or Limitation Options The proposed restriction makes no distinction between polymeric PFAS and other PFAS, but there is no basis for polymeric PFAS to be regulated. Although the persistence of PFAS is cited as the reason for the restriction, it cannot be said that polymers other than plant-derived or biodegradable plastics also degrade completely in nature. What is the rationale for the polymeric PFAS in particular to remain in the environment longer than other polymers? Hazard or exposure In products made with polymeric PFAS, polymeric PFAS exists in a stable state. There is a low risk that particulates of polymeric PFAS will spread or seep into liquids and cause marine pollution. Information on Alternatives Polymeric PFAS has characteristics not found in other polymers, and therefore, we believe that it is irreplaceable. It may be substitutable in terms of only some functions, but in terms of comprehensive functions, it is not a substitute but a degradation. |
| Answer to specific info request 1:  Electronics and semiconductors, Electronics |
| Answer to specific info request 8:  Fluoropolymers (FEP, PFA, ETFE) are used for insulation and sheathing of electric wires and cables used for cryogenic cables. This cable is used, for example, as a power cable for submerged pumps for discharging liquid from storage tanks for liquefied natural gas, liquid hydrogen, and liquid ammonia.The coating materials used in these products are required to have cryogenic properties, flexibility, electrical insulation, and chemical resistance.There are no polymers or other materials that are compatible with these, , so there is no substitute for fluoropolymers.The alternatives shown in Table 8 in the Annex XV report all have insufficient properties for fluoropolymers.For example, EPDM cannot be used due to its insufficient low temperature resistance and chemical resistance. Silicone rubber cannot be used due to its weak chemical resistance and outgassing problems. Other substitutes, such as cross-linked polyethylene, polyethylene, and PVC, cannot be used at all because of their insufficient low-temperature resistance and chemical resistance. The exemplified PEEK cannot be used because its flexibility and low temperature properties are not suitable. Polyamides and polyesters are unsatisfactory in low temperature resistance, chemical resistance and electrical insulation. Thus, at present, there are no materials that can replace fluororesin or fluororubber, and it is unlikely that materials that satisfy these performance requirements will appear on the market within the 18-month transition period. Furthermore, even with a 12-year grace period, it is very difficult. If this restriction is implemented, it will not only cause extremely serious damage to oil alternative energy and electric power supply, but also have a large impact on carbon dioxide emissions, and the situation will be very serious for the industrial world. Furthermore, even if substitutes for these fluoropolymers were developed, it would be extremely difficult to ensure a stable supply even with this 18-month transition period and 12-year grace period, and the impact on society would be extremely large. |

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| 4581 | Date:  2023/06/16 11:55  Content:  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes | General Comments:  Today, fluoropolymers are used in numerous technologies, industrial processes and everyday applications from the aviation industry to transportation, including electrical vehicles, medical devices and energy production to technical apparel to name just a few. They are durable, chemically inert and mechanically strong in harsh conditions. These unique characteristics of fluoropolymers make them a critical material for a broad range of industries and sectors, playing a diverse and crucial role for society, with few, if any, viable alternatives.  Beyond their socio-economic value for European industry, their unique stability means that they are low-risk polymers for human health and their environment. Trying to replace them in their many applications would lead to substitution with alternatives (when available) that do not provide the same advanced performance and safety as fluoropolymers. Banning Fluoropolymers will be the wrong step into the future for our humanity. |
| Answer to specific info request 1:  • Industrial food and feed production • Tubes and catheters • Hydraulic fluids |
| Answer to specific info request 2:  Preliminary information from a recent project initiated by Gujarat Fluorochemicals Limited (GFL), a leading Fluoropolymer manufacturer, and executed by the Karlsruhe Institute of Technology (KIT) in cooperation with Société Générale de Surveillance (SGS) demonstrates clearly that Fluoropolymers are converted to Inorganic Fluorides and Carbon dioxide at standard incineration conditions. The inorganic fluorides mainly include Hydrogen Fluoride and Silicon tetrafluoride. Total organic fluorides (PFAS) were non-detectable with a reporting limit of 0.08 ppm and Trifluoroacetic acid (TFA) was also not detected with a reporting limit of 0.04 ppm. The results confirm that Fluoropolymers at their end of life when incinerated in waste to energy recovery plants do not generate any noticeable levels of PFAS emissions and therefore, pose no risk to human health and the environment. |
| Answer to specific info request 3:  The study involved application samples of the four most sold Fluoropolymers (PTFE, PVDF, PFA and FKM) provided by Pro-K (German association of polymer processors), which were incinerated under standard operating conditions for municipal and industrial waste incineration (850°C – 1100°C for two seconds residence time respectively) and consulted by the German Federal Environment Agency (Umweltbundesamt). Final data set and methodology used are being reviewed and validated by Environmental Standards Inc. The absence of organic fluorides and more specifically PFAS substances in incineration flue gas confirms complete thermal destruction of Fluoropolymers during incineration and therefore it should pave the way for exempting Fluoropolymers from the EU REACH PFAS restriction proposal. |
| Answer to specific info request 4:  • The PTFE/PFA/FEP scraps resulting from manufacturing of hoses are sold to companies that recycle them. • 2500 kg/year |
| Answer to specific info request 5:  • 100 tons/year of PTFE/FEP/PFA • no information on emissions |
| Answer to specific info request 6:  Chemical and pharmaceutical industry Main properties of PTFE/PFA/FEP hoses: • excellent chemical resistance to almost all chemicals; • wide working temperature range (from -70°C to +260°C as a standard); • excellent resistance to ageing and weather conditions; • self-cleaning properties – non-stick surface. Nowadays, hoses made of PTFE/PFA/FEP are used in all sectors of the industry e.g. for steam, hot oil, fuel, paint, adhesives, high pressure gas transfer. In the chemical industry, they are used for loading and unloading of acids, bases, organic solvents and very aggressive chemicals. PTFE hose assemblies ensure highly hygienic transfer and perfectly suit food, cosmetic, pharmaceutical industry and biotechnology. |
| Answer to specific info request 7:  Fluoropolymers are high value chemicals that provide a wide variety of properties in key industrial sectors. These chemicals are indispensable to guarantee the adequate functioning of modern society, with key contributions in safety, decarbonization, and high-tech development. However, fluoropolymers show clearly differentiated properties from other PFAS, and the vast majority of these polymers have been identified as matching the definition of Polymer of Low Concern. Fluoropolymers are not expected to degrade during normal use or at their end of life, and the main concerns related to their manufacture are being successfully addressed by industry, with innovative developments in both safer designs and improvement of abatement techniques to control emissions. |
| Answer to specific info request 8:  Fluoropolymers are used in a wide variety of highly critical applications due to their valuable properties, mainly by industrial actors.2 In the case that the use of fluoropolymers would be banned in Europe, a number of critical sectors would be significantly impacted, which could result in severe damage to the European society. The list below covers just a selection of examples of industries that could be damaged because of this. – Renewable Energy: fluoropolymers are key components in solar panels and wind turbines, where they protect against weather impacts of equipment exposed to e.g., rain and environmental contaminants. In photovoltaic cells, fluoropolymers improve electrical insulation. Furthermore, these materials are critical and absolutely necessary for optimal performance of lithium-ion batteries and hydrogen fuel cells. Without fluoropolymers, these devices will not work efficiently, and the goals of the European Green Deal would be seriously compromised. – Semiconductors: fluoropolymers provide properties that are essential in this use, such as resistance to harsh chemicals that need to be used in themanufacturing process while providing an environment completely free of impurities.No fluoropolymers available will mean that the semiconductor industry will not be able to produce the high-tech microchips that allowfor the development ofmodern (and reduced insize yet powerful) devices such as mobile phones, laptops and many other hightech equipment. – Chemical process industry: due to their unmatched properties in terms of resistance to chemical attack and optimumperformance under wide variations of temperature, fluoropolymers are the only available set of products on the market that allow for adequate performance of many chemical processes.While othermaterials could be used for handling chemical streams, these would need continued maintenance and replacement and what is worse, they would significantly increase the risk of failure and accidents, leading to higher probability of operators and the environment being unexpectedly exposed to highly hazardous chemicals. Fluoropolymers can be found in all kinds of tubing and industrial equipment, as well as joints and gaskets to secure operation and containment of chemicals. – Transport: fluoropolymers contribute to both fuel efficiency (as key components in combustion engines) and safety, playing a key role in systems such as brakes in cars or wing flaps in aircrafts. They are also the best option available (due to their high resistance but also high flexibility) to protect electrical cables in aircrafts, where high reliability of such cables,which can be exposed to thermal as well as chemical pressure, is fundamental. - Food and water treatment: wherever high purity is required, fluoropolymers play an irreplaceable role. These materials are present in water filtration systems (which avoids the need to use chemicals forwater treatment) and also in food processing systems to guarantee adequate sanitary conditions and avoid contamination which could otherwise reach consumers. – Pharmaceutical and medical devices: medical implants that are intended to be used in the human body (catheters, implants) due to their biological compatibility and inertness. Certainly, materials that are used for this purpose are not toxic for human health and, due to their high durability, can last for many years in the body without replacement. Furthermore, the production of medicines and vaccines by the pharma industry require as well ultra purity conditions which can only be achievedwith equipment based on fluoropolymer materials. |

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| 4583 | Date:  2023/06/16 13:04  Content:  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  The use of PTFE as a technical material with unachieved abilities for specific elements such as sealings, wipers or in general can not be replaced. It is critical for a very large sector in the machining industry to be able to use and incorporate those materials. A restriction will have a hugh impace in the availability of all machines with rotating components including critical machines such as wind generators. I request an exemption for the use of PTFE in the machine industry in conjuction with strict regulations on the waste process to contain the PTFE's after use. With this approach, the benefit of the extraordinairy abilities can be used and the impact on the environment is minimized. |

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| 4584 | Date:  2023/06/16 13:20  Content:  Scope or restriction option analysis  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:  American Chamber of Commerce to the European Union (AmCham EU)  Org. country:  Belgium  Attachment:    <redacted> | General Comments:  The European Chemicals Agency (ECHA) is currently discussion the restriction of per- and polyfluoroalkyl (PFAS) substances. To secure long-term European manufacturing, this socio-economic analysis must not only include the impact on specific applications but also the impact on transatlantic trade and foreign long-term investments. Not taking these into account will ultimately have strong repercussions on the EU’s strategic autonomy and on many key policies, including the Green Deal ambitions. Furthermore, ECHA, its committees, the European Commission and EU Member States should review the proposal’s current derogations and assess their enforceability. For many strategic sectors and technologies, derogations are too short or completely missing where no viable alternatives exist. In addition, the proposal does not adequately assess the availability and viability of relevant alternatives. By way of example, further derogations and exemptions are needed for important applications in medical technology, the high-tech sector (eg semiconductors), clean energy (eg hydrogen fuel cells and batteries) and industrial manufacturing. These are among the applications that ensure the continued operation of countless industrial plants that underpin entire value chains in Europe, supporting the green transformation of industry and the goals of the Green Deal. The restriction’s framework should therefore take a proportionate approach to allow for both the achievement of the ambitions laid out in the Net-Zero Industry Act (NZIA), Green Deal and REPowerEU as well as the preservation of human health and the environment. In summary, ECHA must amend the proposal to: • Exclude from the scope of industrial/professional applications which are fundamental for European sovereignty and the implementation of the NZIA, as well as crucial for the cooperation established in the EU-US Trade and Technology Council (TTC) involving batteries, semiconductors/chips, heat pumps, electric vehicles, hydrogen and renewable energy. • Ensure alignment with the main Green Deal principles including ‘Energy Efficiency First’, as embedded in the main legislative pieces of the REPower EU package. • Exclude remanufactured/refurbished/repurposed products and components and allow repairability of products to further the goals of the Circular Economy Action Plan. • Be coherent with other regulatory requirements and legislation, such as the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation and the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation, Fluorinated Greenhouse Gases (F-Gas) Regulation and relevant sectoral legislation . • Exempt those PFAS that have not been shown to pose an ‘unacceptable risk’ such as fluoropolymers, which should be regulated by separate regulation, for example by targeted emissions controls. The proposed outright ban is disproportionate to the risk substances such as fluoropolymers pose. • Amend provisions based on incorrect technical assumptions. Accordingly, raw materials (eg fluorinated surfactants) required for the production of PFAS of low concern and which do not pose an ‘unacceptable risk’ (such as fluoropolymers) should be exempted. • Include a more proportionate approach to thresholds, thereby ensuring an enforceable legislation. • Include a general derogation for uses of PFAS at industrial sites to safeguard important value chains. • Include a review clause for derogations in cases where no alternatives became available in the future. • Consider new and ensure longer derogations that allow the industry to adapt or ensure the exclusion for some uses where alternatives are only at the research and development stage or not suitable in their current form. |

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| 4586 | Date:  2023/06/16 13:53  Content:  Scope or restriction option analysis  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  copyrighted materials | General Comments:  For the following reasons, the use of fluoropolymers as the cladding material for single-mode plastic optical fibers (SI-POF) employing PMMA in the core should be exempted from the proposed regulations.  - Assumptions - SI-POF uses the principle of total internal reflection when light enters from a high refractive index material to a low refractive index material, exceeding the critical angle. Therefore, it has a structure where the high refractive index light guiding material (core) is surrounded by a low refractive index material (cladding), and a numerical aperture (NA), as determined by the following equation, of approximately 0.5 is required,  NA = (n1^2 – n2^2)^(1/2) n1: refractive index of core, n2: refractive index of cladding  - (1) Significance of POF - Compared to glass optical fibers, plastic optical fibers (POF) possess superior mechanical strength and significantly larger diameters. Therefore, when applied in key applications such as inter-equipment communication cables, optical sensors, medical devices, lighting, and automotive components, the use of POF is essential to mitigate potential issues including damage, communication disruptions, malfunctioning sensing systems, and medical accidents due to fiber breakage within the body. (\*Standard Diameter: POF 1000μm, Glass Fiber 125μm)  Hence, substituting glass optical fibers with POF is impracticable, as POF is the indispensable material for these applications. Inter-equipment communication and optical sensors are extensively integrated into various production facilities, including semiconductor manufacturing equipment and industrial machinery, making POF a critically important material. Additionally, POF finds application in numerous medical devices, including those used in ophthalmic surgery, solidifying its status as an essential material within the healthcare industry.  - (2) Significance of PMMA core - The core of POF naturally requires high transparency, and among practical resins, PMMA theoretically possesses the highest level of transparency. Applying resins other than PMMA would result in significant performance deterioration. Therefore, the use of non-PMMA resins is extremely limited to exceptional applications, and PMMA remains the only core resin that meets practical performance requirements.  - (3) Significance of Fluoropolymer cladding - In practical terms, a numerical aperture (NA) of POF is required to be equal to or greater than 0.5. The refractive index of PMMA is 1.492, and when combined with the previously mentioned equation, it is necessary for the refractive index of the cladding to be 1.4 or lower.  NA = (1.492^2 – n2^2)^(1/2) ≥ 0.5 ∴ n2 ≥ 1.405  Considering the Lorentz-Lorenz equation, it can be deduced that only fluoropolymers and silicone satisfy this requirement. However, silicone exhibits extremely poor adhesion with PMMA, making it unsuitable for use as a cladding material. Therefore, apart from fluoropolymers, there are no other materials available for use as the cladding.  - (4) Conclusion - As mentioned earlier, POF is being used as an irreplaceable component in various industries, and its core must be made of PMMA. Therefore, the use of fluoropolymer as the cladding material for POF employing PMMA as the core is essential. Consequently, it is necessary to exempt the use of fluoropolymer as the cladding for POF with PMMA core from the proposed regulations.  \*For details about basic principles and characteristics of POF, please refer to [Ref1]. \*For details about low refractive index polymers, please refer to [Ref2]. |
| Answer to specific info request 1:  Not listed in the Table 9., however, fluoropolymers are generally used as cladding layer of Plastic Optical Fiber, what cannot be replaced by any other materials not containing fluorine. |
| Answer to specific info request 6:  a) Fluoropolymers; estimated from the market size, approximately 100 tons/year. b) The fluorine polymer cladding layer covers the PMMA core of Plastic Optical Fiber. Fluorine polymer exhibits the characteristic of low refractive index; which allows for total internal reflection to occur at the interface due to the refractive index difference with the PMMA core. This enables the realization of plastic optical fibers using PMMA core. c) Several companies as Plastic Optical Fiber manufacturers. Hundreds of companies as primary users. Because Plastic Optical Fiber is widely used; for industrial sensors, medical equipment, data communication, illumination, automotive parts, endoscope products and so on, it is difficult to estimate the number of final users who will be affected by the restriction. For example, fiber optic sensors are used in almost all semiconductor manufacturers. d) Because the refractive index of PMMA is about 1.492, the refractive index of the cladding layer should be 1.40 or lesser to achieve NA 0.5 or more. There is no material that achieves such a low refractive index without fluorine. e) Considering the Lorentz–Lorenz equation, it would be impossible to achieve such a low refractive index without fluorine. f) Impossible to be replaced by non-fluorine polymer. g) Because Plastic Optical Fiber is widely used; for industrial sensors, medical equipment, data communication, illumination, automotive parts, endoscope products and so on, it is difficult to estimate the number of final users who will be affected by the restriction. For example, fiber optic sensors are used in almost all semiconductor manufacturers. |

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| 4587 | Date:  2023/06/16 15:27  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Gujarat Fluorochemicals GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Fluoropolymers for all sectors and (sub-)uses |
| Answer to specific info request 2:  To be submitted separately |
| Answer to specific info request 3:  A study by Conversio in 2022 (a consultancy based in Germany) initiated by Pro-K (Fluoropolymer downstream user association) has shown that at its end of life approximately 85% of all fluoropolymers end up in waste to energy recovery incinerators. A recent project executed by the Karlsruhe Institute of Technology (KIT) in cooperation with Société Générale de Surveillance (SGS) was conducted to assess that fluoropolymers get fully incinerated under representative European municipal incinerators conditions without any formation of short chain or long chain PFAS. The study clearly demonstrated that fluoropolymers are converted to inorganic fluorides and carbon dioxide. The inorganic fluorides detected were hydrogen fluoride. A large majority of samples indicated that long chain PFAS were below levels of 1ng/m3 (>99% of samples associated with 860 deg C condition and >98% of samples associated with 1100 deg C condition). There were no short chain PFAS detected post incineration. TFA was non detectable in all samples with a reporting limit of 14 µg/m3. The results confirm that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment. The main reason to include fluoropolymers in the EU PFAS restriction proposal was persistence (resistance to degradation in the environment) in the environment. The absence of organic fluorides and more specifically PFAS in tests representative of municipal waste incineration confirms complete mineralization of fluoropolymers and provides critical data in support for exempting Fluoropolymers from the EU REACH PFAS restriction proposal. KIT fluoropolymer incineration study is attached. |
| Answer to specific info request 4:  To be submitted separately |
| Answer to specific info request 6:  To be submitted separately |
| Answer to specific info request 8:  To be submitted separately |
| Answer to specific info request 10:  To be submitted separately |

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| 4588 | Date:  2023/06/16 15:59  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Alzchem Trostberg GmbH  Org. country:  Germany | General Comments:  Basically, the present restriction proposal does not take into account the wide range of applications and uses of PFAS or PFAS-containing products in the chemical industry apart from manufacturing those. In case of a comprehensive and timely ban, there will be extensive, negative effects in this branch of industry. The fluoropolymers are contained in very many applications with fundamentally important functions (sealing, hoses, sliding surfaces, in electronic devices, sensors) and are used as auxiliary materials (lubricants or as chemical and heat protection in personal protective equipment). Therefore, those must - at least for industry - be fundamentally excluded from a potential ban on use. Currently there are no adequate alternatives available for all different uses. These products are irreplaceable for the save and compliant operation of chemical plants.  Fluoropolymers are predominantly installed in the plants of the (chemical) industry in an abrasion-resistant manner. Thus, no emissions into the environment are to be expected within the framework of the disposal of the fluoropolymer-containing parts, which is strictly regulated by law. Due to low volatility and low solubility, release to air or into wastewater is unlikely. If the national disposal routes specified for industry in the EU are followed, low-emission destruction or recycling is ensured. The stringent environmental regulations on industrial emissions (IED) and in European waste legislation (WFD) ensure that no significant release occurs from industry. The contribution to release and environmental impact from the industrial sector is therefore low.  The replacement of all e.g. PTFE or perfluoroether applications in the affected chemical plants (100%) within the proposed deadlines is neither technically nor financially feasible for the European industry due to the large number of applications. In addition, alternatives for all application areas cannot be developed, tested and approved in the short transition period envisaged (pharmaceuticals, food and feed production, emissions legislation). A general restriction or ban on fluoropolymers classified by the OECD as Polymer of Low Concern (PLC) is not comprehensible. The focus of the restriction should be on volatile or mobile substances and non-essential or substitutable applications that have relevant emissions and a significant, negative impact on the environment, humans or animals. Irreplaceable industrial applications that make little measurable contribution to overall PFAS emissions would be massively hampered by a ban or restriction, with new risks related to plant safety due to less effective, less chemically resistant, and untested alternatives. Ultimately, due to the immense investment costs to be expected, the competitiveness of the European chemical industry would be further reduced and the existing, very high safety and environmental protection level of European chemical plants would be endangered due to the lack of adequate alternatives for the diverse applications. |
| Answer to specific info request 1:  Unfortunately, the chemical industry has not been considered as a separate sector in the present restriction proposal, although the impact on this sector as well as on the pharmaceutical sector is devastating due to the large number of uses, especially with regard to fluoropolymers. Affectedness of our company for the following applications of Table 9: - Most important application: "Fluoropolymer applications". An unlimited exemption is needed for this area. A large number of specialized uses are possible only because of the specific material properties (inert, chemically resistant, durable, temperature and pressure stable as coatings for aggregates and piping, hoses and in personal protective equipment) and the approvals granted on this basis for seals, flanges, valves, use in electronic components, equipment, sensors (no 1:1 replacement is possible). In 95-100% of our chemical plants fluoropolymers are used and installed, either directly as coating material for pipelines and aggregates (e.g. in multi-purpose plants when using a wide variety of chemicals) or indirectly when using stainless steel pipelines, which can only be operated safely and in compliance with the law (TA-Luft) with PTFE gaskets and flanges, valves, ball valves (>95%). Furthermore, in 100% of our plants fluoropolymers are used in electronic components and measuring devices. - The exemption proposed so far only for the production of PFAS active ingredients (animal, human, biocides, pesticides) is not sufficient, but must be extended to include the associated raw materials, intermediates and intermediate products, otherwise further production of the active ingredients by the chemical or pharmaceutical industry in the EU is not possible. Further applications within our company: - TULAC (Annex E.2.2. incl. PPE): Use as personal protective equipment (production and firefighting), fluoropolymers should be exempted from the restriction in PPE indefinitely, as there is no such durable substitute in terms of chemical resistance and heat - Technical Textiles (Textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence): Fluoropolymers are used as filter material in various industrial applications for product extraction, for (ultra) filtration of waste water and as membranes in manufacturing processes (e.g. membrane process hydrochloric acid): 5 years transitional period is too short for the numerous different applications and there should be an unlimited exception, as the risk of emissions is also low due to controlled waste disposal in the industrial sector. - Food contact materials (E.2.3) in industrial food and feed contact production: Fluoropolymers used in plant components, piping (> 50% of piping and in seals, ball valves, valves and as special lubricants for high performance pumps and equipment with necessary product approvals for this sector) - Use of Paper & board packaging and Plastic packaging (only use, no production): Coated paperboard and plastic foils are used for product packaging. - Applications of fluorinated gases (Annex E.2.8.), Refrigeration below -50°C: In air conditioning and heat pumps (in use in installed equipment, replacements must be tested in detail for each application and has to be provided by manufacturers) - Insulating gas in electrical equipment (Insulating gases in high-voltage switchgear above 145 kV): Modern electrical distribution stations contain fluorinated gases. - Fire suppressants (largely already replaced as fire extinguishing agents, but indirectly as additives in installed equipment still in use and necessary) - Cleaning and heat transfer, engineered fluids: The use of fluorinated heat transfer fluids in heating cooling systems in chemical plants, substitution and replacement of the heating-cooling-systems must be planned, i.e. at least 12.5 years of exception are necessary. Also in this case, with the exception of rare malfunctions, a release through industrial applications and the strictly regulated waste sector in the industry is very unlikely. - Transport (Annex E.2.10.) --> Use of fluoropolymers for transport of our products in coatings of hoses, use as gaskets, joints and in flanges, in electronic equipment as well as in safety equipment of vehicles, as far as not already mentioned by other parts of the restrictions (e.g. lubricants, electronic equipment and TULAC) - Hydraulic Fluids: These are in use in our facilities and must be replaced. There is no foreseeable release during use or at end of life beyond the strictly regulated waste area. These should continue to be exempted indefinitely. - Transport refrigeration (Refrigerants in transport refrigeration other than in marine applications): Use in refrigerated transport of sensitive chemicals, a release except in case of accidents is not foreseeable and should therefore continue to be exempted indefinitely. - Use of fluoropolymers in electronics and semiconductors (Annex E.2.11.), see Fluoropolymers: In use in all electronic equipment, a release of fluoropolymers is not foreseeable with controlled disposal in the industrial sector. - Energy sector (Annex E.2.12.): Proton-exchange membranes (PEM) are both under development and in planning for the larger plant. An unlimited exemption is inevitable due to the properties for the development of new processes and the energy transition. - Use of Lubricants (Annex E.2.14.): The use of specialized, oxidation-insensitive (=long-lasting!) fluorinated lubricants in special pumps is prescribed by the manufacturers for safe and long-term operation, approved replacement lubricants must be developed and provided (especially in multi-purpose plants), therefore the extension of the transition period to at least 12 years is mandatory. Without the multiple use of fluoropolymers, many processes under severe conditions (in corrosive media, at high temperature up to 250 °C and high pressure or the use of volatile solvents such as dichloromethane) are no longer possible in Europe and a relocation of production branches outside Europe takes place. As the environmental protection standards mostly are lower outside Europe, an increased release of chemicals in other regions then will occur (with the release not only of fluorine-containing chemicals, but of chemicals of all kinds) and a negative effect on emissions is achieved. This should be taken into account when restrictions are imposed at EU level. |
| Answer to specific info request 2:  - Information can be provided for the production of active ingredients (veterinary medicines) and on the control of emissions generated in the process (compliance with emission limits at the plant and after incineration in the exhaust gas incineration plant after treatment (<0.1 mg/m³ with threshold value of 1 mg/m³ F determined as HF) and on waste from production, that is collected and disposed of via a special plant. The percentage of emissions at all plants is regularly monitored and is below the authorized TA-Luft thresholds. By controlled post-combustion of these collected exhaust gases in a waste gas purification plant with control of the Fluorine values, the emission <0.1 mg/m³ F can be safely maintained (further details on request). - The disposal of plant components containing fluoropolymers is clearly regulated by the German “Kreislaufwirtschaftsgesetz”. For a release during the use of fluoropolymers, the values of the annual analyses of products on impurities such as heavy metals in relation to Fluorine can be used as an evidence that no measurable abrasion to the products occurs during use. - Incineration at the end of the life cycle (waste incineration above 850°C ensures complete decomposition of the fluorinated polymers) and proper treatment of the residues (exhaust gas and residue) via national disposal routes specified for the industry by the EU ensure that no emissions are to be expected during normal operation. - In addition during approval procedures for the food and feed sector, it was ensured that no discharge/abrasion or entry of fluoropolymers into the product takes place, as otherwise the approval would not have been granted. In addition the Final Report 92/ 2023 „SumPFAS –Besorgniserregenden neuen per- und polyfluorierten Stoffen auf der Spur“(SumPFAS –Concerning new per- and polyfluorinated substances on the track) from German Umweltbundesamt clearly states that the temporal trend monitoring showed that the PFAS load of suspended solids in German streams decreased between 2005 and 2019. This clearly shows that by conscious handling, a reduction of emissions is possible without a ban. |
| Answer to specific info request 3:  Since waste disposal in the industrial environment is clearly regulated by law and wastes are specifically separated and sent for controlled disposal (part of the permit for the operation of the plants!), an uncontrolled release of PFAS or fluoropolymers is not to be expected. All fluoropolymer-containing plant components in the industrial environment are disposed of at the end of their life cycle in accordance with the strict waste regulations of the member states, which are also meticulously controlled (see question no. 2). Therefore, a general restriction or ban on fluoropolymers classified by the OECD as Polymer of Low Concern (PLC) is not comprehensible. |
| Answer to specific info request 5:  At one of our sites, PFAS are used as intermediates and active ingredients (veterinary medicines and biocides) are produced from them, which would be exempt from the proposed restriction. Emissions and waste from production are monitored across all stages and do not result in the release of PFAS. A limit value of 1.0 mg/m³ for fluorine/-HF is defined for the waste gas purification plant, which has been continuously undercut for years, also during production of the active ingredient. Since 2020, the measured value has been continuously at or below 10% of the measured value at 0.02 to max 0.1 mg/m³ F. Increased abrasion or input via raw materials of Fluorine from other plants at the site would also be detected by an increase in the measured value for HF after incineration. |
| Answer to specific info request 6:  With the currently proposed exemption only for the manufacture of the active ingredients, without including the manufacture of the precursors and intermediates, this exemption is not usable for the industry. Thus, dependence on ex-EU imports will be increased for these products. Manufacturing only the final stage of the active ingredients in the EU will result in moving all production out of the EU for most of the exempted uses. The inclusion of intermediates and raw materials in the active ingredient manufacturing exemption is strongly recommended, otherwise it is useless and cannot be implemented. 100% of the chemical and pharmaceutical sectors use other PFAS in addition to fluorine-containing raw materials to manufacture active ingredients exempted from the restriction (it is hard to imagine a fluorine-containing chemical handling facility without the use of fluoropolymers in seals, hoses, coatings, and in electronic devices). The sectors of chemical, pharmaceutical, and biocide/plant protection production are currently not considered as manufacturing facilities in the restriction proposal. 100% of chemical and active ingredient manufacturers (even without Fluorine in the molecule) are affected by a ban on fluoropolymers. - Without the use of fluoropolymers, neither the production of the above-mentioned fluorine-containing active ingredients in the EU is reasonably possible, nor the production of substances that can only be manufactured under strict conditions (pH, organic solvents, temperature). This means that in addition to PFAS, many other basic and specialty chemicals will no longer be produced in Europe. - To find reasonable substitutes for fluoropolymers with comparable inert properties and necessary approvals (USP, NSF, FDA, TA-Luft etc.) for ALL applications in the given time frame seems impossible (coatings of aggregates, pipes, use in valves and gaskets, electronic devices, hoses, PPE etc.). The ban on the use of fluoropolymers in the industrial environment, which has not yet been discussed, is incomprehensible, since the use and disposal of waste containing fluorine is also regulated via the various legal areas, and it can be ensured via additional controls or measurements, if necessary, that emissions from industry are minimal. Without this exemption, massive losses and closures are to be expected for the entire chemical and pharmaceutical industry, and dependence on imports to the EU will increase. And if chemical production is relocated from Europe to countries with less environmental legislation, no positive effect for the environment can be achieved. Replacing the fluoropolymers in all plants (seals, valves, coatings, hoses, measuring instruments and sensors) would require investments of 25-30% of the annual turnover, if alternatives exist and are available in the timeframe (if all affected companies replace at the same time), which cannot be recovered within the timeframes specified for listed companies and would therefore lead to shutdowns (sites and individual plants or areas). These costs do not yet include plant shutdowns and longer-term supply outages. A medium-sized company like Alzchem would have no chance of surviving this economically. In an international comparison, almost no EU manufacturer would be competitive if the additional costs were apportioned. In our view, the extension of the exemption to include the use of fluoropolymers in the industrial sector is absolutely necessary, especially since the proportion of direct PFAS emissions from this sector is negligible. Likewise, the use of PFAS in the laboratory and analytical sector with trifluoroacetic acid for sample preparation for mass spectrometry, as a mobile phase in HPLC and in protein analysis, as well as the use of PFAS standards for quantification is negligible in terms of emissions (the waste is also collected there) and alternatives for the various applications are currently not known. - An unlimited exemption for all laboratory applications and also for new developments is necessary. - A general ban on PFAS applications in Europe will lead to research and development in this area no longer taking place, which is to be seen as extremely disadvantageous in international competition and also severely restricts solution approaches for the future. Safe uses and those without or with negligible release and emission of PFAS must be further possible and a restriction of research does not make sense in the long term. |
| Answer to specific info request 7:  The direct and indirect effects of the ban on fluoropolymers on the chemical industry have not been considered so far and, if removed, will lead to a collapse of the entire sector. The low potential for emissions from fluoropolymers must be taken into account when defining exemptions, as must a loss of safety when switching to substitute materials, if available at all (see question 6). Due to the large number of applications and uses, it is hardly possible to find consistent and safe alternatives for all of them and to achieve the necessary approvals within the specified, very short transition periods. In addition, the production of fluoropolymers in Europe must also remain possible, otherwise dependence on non-European imports will continue to increase. A general restriction of research and development for PFAS seems also not sensible. In addition, we fully support the coordinated statements of the VCI. |
| Answer to specific info request 8:  The chemical industry is not yet covered as a separate sector and is nevertheless extremely affected by the restriction if there is no exemption for the use of fluoropolymers (see paragraphs above). We also fully support the statements in the VCI statement. Use of fluoropolymers as technical textiles: - Personal Protective Equipment: contrary to the statement of the alternatives, it is NOT ensured that suitable fluorine-free substitute materials are available for high temperatures and for handling corrosive and possibly very toxic substances in the production of chemicals, active pharmaceutical ingredients (human and animal) as well as for biocides and pesticides. Any change from known and established fluoropolymers to new groups of substances poses risks for workers in occupational health and safety in case of possible contact and sufficient testing is necessary before the changeover for the complete chemical industry. Due to the large number of substances, an unlimited exemption for fluoropolymers in PPE is proposed. - Filter materials are in various chemical processes for isolation of products or also for treatment/concentration of wastewater fractions. Chemically resistant PTFE are used in membrane processes for the production of basic chemicals (e.g. HCl, sulfuric acid), an elimination will also lead to the fact that these chemicals can no longer be produced in Europe. |
| Answer to specific info request 9:  No release from fluoropolymers from the industrial environment due to controlled waste separation and targeted incineration at 850°C with subsequent waste gas scrubbing and treatment. This type of disposal and, if necessary, subsequent recycling does not cause any problem due to poor degradability. |

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| 4589 | Date:  2023/06/16 16:23  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Gujarat Fluorochemicals GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Fluoropolymers are very stable materials, but persistency alone is not an appropriate measure of potential human health or environmental risk. Persistence in the environment does not indicate that the substance would accumulate in organisms, nor that environmental levels would rise to such an extent that exposure would result in toxicity. The PBT criteria established under REACH has always considered the characteristics of both persistency and bioaccumulation together, as indicators of potential risk (i.e., toxicity), which is not the case in fluoropolymers. Moreover, persistency, or stability, is the characteristic behind the much sought after properties that fluoropolymers bring to numerous industrial applications (e.g., related to chemical and temperature resistance or durability of products). Furthermore, any alternative substances that may be considered as potential substitutes for fluoropolymers, and which should perform at levels at least close to those of fluoropolymers are likely to be persistent too. This is described in a recent (eco-)toxicity read-across report written by GSI Environmental USA, providing information on the lack of concerns related to fluoropolymers. The report is attached. |

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| 4590 | Date:  2023/06/16 17:49  Content:  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Belgium  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  Energy efficiency will be impacted as we will need to stop with premium products and will have to work with products that have lower thermal insulation values. This will increase insulation thicknesses and further reduce living comfort. Moreover, if the construction does not allow the entire increased insulation thickness to be installed, the dwelling might no longer be able to meet prevailing application standards, as well as future standards entailing the European Green Deal, and its residents might miss out on premiums and financial compensations. Overall cost for installing thermal insulation will increase as any alternative solution will require more man hour to install. The foam blowing agent is an exclusive professional product used as a thermal insulation with highest insulation value and with decades life expectation. Our company has invested a lot of time and resources in meeting the European F-Gas regulation by replacing its HFC portfolio with HFO technology, resulting in a better performing product with higher added-value to the end user and its environment. It is our believe that imposing a new restriction, partially contradicting existing European regulation and based on a too broad interpretation of the chemical component PFAS, with a timeline for implementation too short to be operationally and commercially feasible for the industries involved does not constitute a constructive and realistic route to market, irrespective of the underlying noble and justified intentions. |
| Answer to specific info request 1:  Foam blowing agent for closed cell in-situ PU foam for thermal insulation. Propellant for one component PU foam for filling, sealing, insulating and bonding. |
| Answer to specific info request 6:  Unlike HFC blowing agents, HFO blowing agents for closed cell in-situ PU foam for thermal insulation have a very low GWP (compliant with the F-Gas regulation), they are non-flammable and they have a very good thermal insulation value. We see a sharp rise in demand for HFO blowing agents due to the EU energy saving- and global warming targets. Potential alternatives to the HFO-blown closed cell in-situ PU foam thermal insulation are pentane based PUR- and PIR insulation panels. For the above in-situ application as such, there exist no alternatives at the time. Most likely, worst case REACH restriction scenario for the HFO blowing agent will be discontinuation of PFAS dependent operations. The transition time to complete process changes related to an HFO blowing agent alternative technology, if viable at all, will be at least 80 months as this process is not started yet because this technology is not available yet. This transition time includes R&D, product testing and -certification, investments in production capacity and storage facility. As reference indication, the HFC- to HFO blowing agent and propellant transition took more than 5 years to get all products developed, approved, certified and operational in place. Also, the financial impact of replacing a mature technology by a start-up technology should not be neglected. Unlike HFC propellants, HFO propellants for one component PU foam for filling, sealing, insulating and bonding have a very low GWP (compliant with the F-Gas regulation), they are non-flammable and they have a very good thermal insulation value. HFC propellants will phase out and will in part be substituted by HFO propellants. Main share of HFC propellants will further move to flammable propellants. Potential alternatives to the HFO propellants in one component foams are propane, butane and DME. It is cheaper to use such flammable propellants like propane, DME and isobutane. Most likely, worst case REACH restriction scenario for the HFO propellant will be discontinuation of PFAS dependent operations or chemical substitution. The transition time to complete process changes related to an HFO propellant alternative technology, if viable at all, will be at least 80 months as this process is not started yet because this technology is not available yet. This transition time includes R&D, product testing and -certification, investments in production capacity and storage facility. |

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| 4591 | Date:  2023/06/16 17:49  Content:  Scope or restriction option analysis  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  TEPPFA (The EU Plastic Pipes and Fittings Assication)  Org. country:  Belgium  Attachment: | General Comments:  In our opinion, the derogation timelines are therefore too short in view of the required discovery and implementation of viable alternatives for most fluoropolymer uses identified in our sector. TEPPFA members and industry are continuously looking for innovative materials for their applications. Until now, no viable alternatives to fluoropolymers could be found with the same Key Performance Criteria (KPCs). Therefore, an unlimited derogation for fluoropolymers for complete piping systems (including components, control & measurement instruments, tools, welding machines) as well as for fluoropolymers used in industrial settings (manufacturing equipment in industrial plants) should be granted. |
| Answer to specific info request 1:  See Section IV |
| Answer to specific info request 2:  A 2nd submission might address that topic |
| Answer to specific info request 3:  A 2nd submission might address that topic |
| Answer to specific info request 5:  A 2nd submission might address that topic |
| Answer to specific info request 6:  A 2nd submission might address that topic |
| Answer to specific info request 7:  A 2nd submission might address that topic |
| Answer to specific info request 8:  A 2nd submission might address that topic |

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| 4592 | Date:  2023/06/19 05:27  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  This information has our commercial interests, including intellectual property, would be undermined. | General Comments:  We are a fluoropolymer processing manufacturer who handles PTFE, PFA, FEP etc. Fluoropolymers are socio-economically essential and no-hazardous under appropriate conditions. We believe that the proposed resrtiction is extremley excessive to regulate all PFAS as one category despite the variety of types. We supports the two statements made by JFIA and FCJ on the issues of proposed restriction, as per attached in Section IV. We can not see that all sectors of fluoropolymer applications are reflected in the dossier. Fluoropolymers are used in many situations as secondary materials in the manufacturing process rather than for direct use. There are too many situations to describe each one. In addition, applications for secondary materials in B to B are used in limited spaces and can be managed appropriately. Therefore, restrictions on the use of these secondary materials have a very large impact on economic activity, but the effect on environmental risk reduction is limited. We propose to create the sector of industrial applications. Here within we request a derogation of fluoropolymers as a secondary materials for manufacturing process. |
| Answer to specific info request 1:  There are no sufficient sectors and (sub)-uses available at this time. We suggest to establish industrial secondary materials for manufacturing process as a new sector. We consider it to be a missing use as per the following Specific Information Requests 6. |
| Answer to specific info request 6:  Please see attached confidential file in the Section V. |

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| 4593 | Date:  2023/06/19 05:41  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Rinnai Corporation  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  The protection of your commercial interests, including intellectual property, would be undermined. | General Comments:  - |
| Answer to specific info request 1:  Other niche applications |
| Answer to specific info request 6:  Water seals used in the water passages of water heaters and boilers. About 34,000 water heaters and about 6,600 boilers are imported into the EU each year. a. Type of PFAS ; FKMs,Bisphenol AF. b. Key functions of PFAS ; Prevents leakage of water and hot water as a water seal in the water passage of water heaters and boilers. It provides functionality and safety up to the product life (approximately 10 years) without being degraded by water or chlorine for disinfection in an environment reaching 85 deg.C. g. Substitution is not technically or economically feasible ; Water seals in the water passages of water heaters and boilers require heat resistance of about 85deg.C and water resistance. In addition, high chemical resistance is required due to contact with chlorine-containing water for disinfection. There is no suitable alternative material that meets all of these required properties. Since there are no alternative materials or alternative technologies, inappropriate alternatives will certainly shorten the life of products, increase waste due to repairs and replacements, and place a burden on the environment. Failure to satisfy all the required properties will lead to environmental impacts due to water leakage and, in the worst case, product-related accidents and fires that will affect human life. Also, by exempting spare parts from application, it is possible to reduce the disposal of products that impose a burden on the environment. Therefore, continuous use of this product with Time-unlimited is essential. |

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| 4594 | Date:  2023/06/19 05:55  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Rinnai Corporation  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  The protection of your commercial interests, including intellectual property, would be undermined. | General Comments:  - |
| Answer to specific info request 1:  Other niche applications |
| Answer to specific info request 6:  Fluorine grease used in the water passages of water heaters and boilers. About 34,000 water heaters and about 6,600 boilers are imported into the EU each year. a. Type of PFAS ; PTFE,Perfluoropolyether. b. Key functions of PFAS ; Fluorine grease is applied to improve the slidability of parts that control water flow in the water passages of water heaters and boilers. It provides functionality and safety up to the product life (approximately 10 years) without degraded by water, chlorine for disinfection, or salt water in an environment reaching 85 deg.C. g. Substitution is not technically or economically feasible ; The sliding parts of the water passages of water heaters and boilers require heat resistance of about 85 deg.C and water resistance. There is no suitable alternative material that meets all of these required properties. Since there are no alternative materials or alternative technologies, inappropriate alternatives will certainly shorten the life of products, increase waste due to repairs and replacements, and place a burden on the environment. If all the necessary characteristics cannot be met, the water volume cannot be controlled and the water temperature cannot be controlled properly, which in the worst case can lead to burns. Also, by exempting spare parts from application, it is possible to reduce the disposal of products that impose a burden on the environment. Therefore, continuous use of this product with Time-unlimited is essential. |

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| 4595 | Date:  2023/06/19 10:01  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  Japan Phenolic Form Association  Org. country:  Japan  Attachment: | General Comments:  June 19, 2023  Comment on Proposed Restriction of PFAS  Japan Phenolic Form Association (JPFA)   We, the Japan Phenolic Foam Association (JPFA), have worked tirelessly to develop and promote high-performance insulation materials. We have supported EU's ambitious attempts to reduce risks from hazardous substances and have sincerely responded to actual measures to meet the requirements of EU chemical regulations such as REACH. However, we believe that the proposed restriction of PFAS (Per- and Polyfluoroalkyl substances) proposed by 5 European countries is an excessive measure because it restricts more than 10,000 of organofluorine compounds (PFAS) on the grouping basis that they are persistent as substances of concern equivalent to the already regulated PFOS and PFOA. Therefore, the JPFA fully supports the statement made by FCJ on the issues of proposed restriction,as per attached in Section IV. We would also like to add that, from an architectural point of view, the proposed restrictions could lead to the following situations.  ■Hindering the development of improved insulation performance. With the urgent need for decarbonisation and energy saving in new and existing residential and non-residential buildings, there is a need to improve the insulation performance of the building envelope, which is closely related to air conditioning energy, which accounts for around 30% (in Japan) of a building's operational energy. HFO gas, one of the PFAS, is widely used as a foaming gas for insulation. The thermal conductivity of phenolic foam insulation currently on the market in the World is 18-22 mW/(m-K), with the high-performance 18 mW/(m-K) products using HFO as the foaming gas (20 mW/(m-K) is HC gas). In Japan 2022 saw a revision of JIS A 9521, with a ranking of 16 mW/(m-K) and 17 mW/(m-K) were established. This rank was expected to improve the performance of insulation materials in the future, and manufacturers are developing insulation materials with HFO gas as a candidate foaming gas. The proposed restrictions may hinder that performance-enhancing development.   ■Increase GHG emissions from buildings. In its Guidelines on Housing and Health, the World Health Organisation (WHO) strongly recommends an indoor temperature of at least 18°C to protect occupants from the health effects of cold weather, and recommends that homes in areas with cold seasons should be conditionally insulated when newly built or renovated\*1. Public Health England reports that lower temperatures pose a health risk\*2. If the indoor temperatures recommended in the proposed restrictions are to be maintained, the thickness of the building envelope without HFO will be 10-20% thicker than that with HFO. This means that the structural frame will be larger in proportion to the thickness of the envelope, which means a significant increase in GHGs during construction. Also, if the structural frame is of the same dimensions, the insulation performance will be reduced by 10-20%, which means that the operational energy of the building will increase proportionally. We think that this situation is not what ECHA would like to see.  Reference: \*1 WHO Housing and health guidelines : World Health Organization 2018.11 \*2 Cold Weather Plan For England Making the Case : Public Health England |
| Answer to specific info request 1:  building insulation |

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| 4596 | Date:  2023/06/19 10:36  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Description of analytical methods  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  There is no suitable alternative material that meets all the required properties.  Fluor rubber and fluor resin contribute to automobile safety, contribute to industrial decarbonization, and prevent environmental pollution. Fluor rubber and fluor resin should be excluded because there is no evidence of harm.  6 months is not enough public consultation and 18 months is too short a transition period.  Annex XV report (Summary) Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) Column 2 Conditions of restriction 2 There is no instruction specified an internationally accepted method of analysis. It should be specified the PFAS to be targeted for analysis, subject to the existence of an internationally accepted method of analysis. |
| Answer to specific info request 1:  sectors: E.2.14. uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.3.Grease CAS RN: raw materials 252237-40-4 25291-17-2 17527-29-6 1189053-50-6 1219035-32-1 13252-13-6 37382-64-2 51798-33-5 163702-08-7 163702-07-6 163702-06-5 163702-05-4 132182-92-4 428-59-1 116-15-4 116-14-3 75-45-6 7594-51-6 1623-05-8 10493-43-3 2070-70-4 30320-29-7 30320-27-5 30320-26-4 1644-10-6 1998-53-4 2062-98-8 2641-34-1 13252-14-7 26131-32-8 14548-74-4 174080-50-3 27639-98-1 131628-36-9 646029-82-5 646029-84-7 646029-85-8 34761-47-2 133609-46-8 13252-15-8 27617-34-1 51798-33-5 850734-65-5 2416268-96-5 25038-02-2 204270-10-0 |
| Answer to specific info request 8:  Uses: ANNEX XV Conditions of restriction 5 s) ANNEX A.3.15.1.5. Release-agents Function: To improve mould release of moulded products. Quantity used: 10-100 t/y Environmental emissions: No (disposed of as industrial waste). Usefulness, advantages. The use of fluorinated release-agents brings significant benefits to the social value chain. Fluorinated release agents (especially fluorinated telomers) are important application examples due to the unique characteristics of fluorine. The product is an indispensable industrial material and sub-material in the synthetic rubber/resin processing process, including fluoroelastomers. Alternative materials. In the manufacturing process of semiconductor materials, which are indispensable for the advanced information society expected in the future, they are also important. Non-fluorinated release agents, especially silicone release agents, cannot be used in the manufacturing process of semiconductor components due to their electrical properties. In addition, non-fluorinated mould release agents do not fulfil their performance requirements at all, making the production of many semiconductor components difficult. Alternative materials to fluorinated release agents have been evaluated and found that they often fail to meet the key performance characteristics of fluorinated release agent-based materials, and often fail to meet several properties (e.g. surface tension; 11 mN/m) and ranges that are time unlimited for applications where fluorinated release agent-based materials are required. The fluorinated release agents currently on the market are indispensable. Problems and disadvantages of restricting PFAS The following are some of the consequences of extensive PFAS restrictions (including PFHxA and PFBA restrictions). Critical impact on the material (synthetic rubber/resin) processing process. Unacceptable deterioration of production costs due to the use of alternative materials due to significantly lower performance levels and life expectancy. Significant increase in waste material due to processing defects. Overall, this leads to an increase in waste. The use of alternative materials may lead to a significant increase in the amount of material used, which may have an impact on the human body and the environment. Safety assessment of PFASs. The fluorinated mould release agents and fluorotelomer, the raw material for fluorinated mould release agents, have shown negative results in mutagenicity tests, and the proposed restrictions do not immediately apply to their handling. [Contents of appeal + page 11]. We request that fluorinated mould release agents and fluorotelomer, the raw material for fluorinated mould release agents, be exempted from the PFAS regulation as an time unlimited use in recognition of their importance in the processing of rubber/resin products (materials). |

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| 4599 | Date:  2023/06/19 13:16  Content:  Environmental emissions  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Prelon Dichtsystem GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Prelon Dichtsystem GmbH uses 90 to 95 % PTFE for the production of seals (especially shaft seals). The economic, supply and social leverage of our PTFE applications is extreme. The Prelon PTFE seals take on a key function in machines, processes and apparatus, which enable and ensure an almost unnameable number of products and immense production quantities in the first place. Key function means: at first glance, these are small, seemingly insignificant parts, which, however, make a multitude of procedures and production processes …  … possible at all. (handling chemical intermediates or cleaning agents that are hazardous to people, compliance with hygiene regulations, process steps that are at risk of explosion: inert properties, coefficient of friction, dispensing with lubricants) and/or   would have to be throttled down to a fraction of their output.   In other applications, without the PTFE seals of the   In terms of occupational health and safety, this is assured. Selected applications of PRELON PTFE shaft seals Chemical industry / food industry / medical and pharmaceutical industry Centrifuges for ... ... separation of substances in the liquid phase in the production of raw materials and foodstuffs High sliding speeds, long service life, hygiene, universal resistance required PTFE properties (effects): • inert - chemical resistance (occupational safety) (environmental protection) • low coefficient of friction (energy efficiency) • very long service life (sustainability, resource conservation) • thermal resistance Agitators and mixers ... ...with chemically different, constantly changing liquids / bulk materials. The shaft seals serve to safely contain hazardous intermediates and aggressive chemical compounds. Pumps ... for silos and silo vehicles with chemically different, constantly changing liquids / bulk materials. Sealing of conveyors and roller tables in the food industry Lubrication-free sealing of roller tables in the food industry No lubrication, therefore no contamination and compliance with hygiene, Resistance to aggressive cleaning agents (acids, bases) to ensure hygiene Long-term durability Inert - self-lubricating - hygienic - low friction - sustainable Electric motors for drive in food / medical and pharmaceutical processes ... with lubrication-free motor shaft seal, resistant to acidic and alkaline cleaning agents low-migration towards any foodstuffs required PTFE properties (effects): • inert - chemical resistance (industrial safety) (environmental protection) • low coefficient of friction (energy efficiency) • very long service life (sustainability, resource conservation) • hygienic (health care) • - thermal resistance Textile industry: Chemical baths / plant For the treatment / finishing / dyeing of textiles, the fabric webs are conveyed through baths. The conveying mechanism in baths with various changing chemical liquids must be sealed. required PTFE properties (effects): • - inert - chemical resistance (occupational safety) (environmental protection) • - low coefficient of friction (energy efficiency) • - very long service life (sustainability, conserves resources) Bitumen processors / road construction: Bitumen pumps ... ...had not been really sealable until now, leakages were accepted At high temperatures, under pressure, a low-viscosity medium (bitumen) cannot be sealed with any other sealing material. Chemical resistance - Thermal resistance - Low friction required PTFE properties (importance): • - inert - chemical resistance (industrial safety) (environmental protection) • - low coefficient of friction (energy efficiency) • - very long service life (sustainability, resource conservation) • - thermal resistance (occupational safety) (environmental protection) Metal industry, e.g. steel production Sealing of roller tables in (transport of red-hot steel slabs 900°C) Cooled moving rollers have to move loads of several thousand kilos of red-hot metal. Grease prevention, thus no more grease fires (work safety in high-temperature environments), Long-life sealing ensures high work safety under extreme thermal and mechanical conditions. Self-lubricating - Low friction - Temperature resistance required PTFE properties (importance): • - inert - chemical resistance (industrial safety) (environmental protection) • - low coefficient of friction (energy efficiency) • - very long service life (sustainability, resource conservation) • - thermal resistance (occupational safety) (environmental protection) The entire mechanical and plant engineering, vehicle and automotive industries (regardless of whether combustion engine or e-drive or hydrogen drive) are bursting with applications with PTFE seals that have no alternative. Our company can only become insolvent in the event of a ban on PTFE. There is no alternative material PTFE is such a low-risk product with benefits for humans and the environment that cannot be overestimated. The compatibility of PTFE for humans and the environment has been proven by extensive migration tests and animal experiments (USA: USP class VI). Piston and rod seals aggressive oils (bio-oils) with additives (bio-oils) High temperatures, high pressures Significantly longer service life B) Examples of FKM seals 200°C - Cooking ovens for aircraft - Waste water pumps for dishwashers - Underwater motors Ship propulsion systems - Metering systems 2-component adhesives FKM or PTFE only Chemical resistance - Exhaust air systems - Fans chemical gases |
| Answer to specific info request 2:  Firma Prelon stellt vorzugsweise Dichtsysteme her, die nach end-of-life bei Wartungsarbeiten oder im Fall des end-of-life der Maschine über Stahlrecycling entsorgt werden. Dabei ist sichergestellt, dass die Produkte der Firma Prelon einer Temperaturbehandlung > 800°C und > 3sec. unterworfen werden. Unter diesen Bedingungen werden Fluorpolymerbauteile mineralisiert, d.h. in CaF2 überführt. Es entstehen dabei keine nennenswerten toxischen Emissionsgase. Siehe hierzu Bericht des pro-k über "Incineration study". |
| Answer to specific info request 3:  Siehe hierzu Bericht des pro-k über "Incineration study". |
| Answer to specific info request 4:  Derzeit ist als neue Methode des chemischen Recyclings das upcycling-Verfahren im Aufbau. Siehe hierzu Eingabe der Firma Element9. Ich gehe davon aus, dass die Produkte der Firma Prelon im wesentlichen dem Stahlrecyclingweg folgen. |
| Answer to specific info request 5:  Die Firma Prelon verarbeitet derzeit 2 to Fluorpolymere pro Jahr. Aufgrund der Tatsache der speziellen Anforderungsprofile der Verwendungen sehen wir keine Möglichkeit der Substitution in diesen Anwendungen. |
| Answer to specific info request 6:  Siehe Beschreibungen der Produkte der Firma Prelon s.o. Prelon stellt Dichtungen schwerpunktmäßig dynamische Dichtungen für den allgemeinen und speziellen Bau von Maschinen in der chemischen Industrie, Metallindustrie, Strassenbau, Prozessindustrie, Lebensmittel und Pharmaindustrie u.a. her. |
| Answer to specific info request 7:  Die derzeit von der Firma Prelon verwendeten Werkstoffe wurden nach den 13 PLC-Kriterien der OECD sowie weiteren Prelon-spezifischen Anforderungskriterien charakterisiert und möglichen Werkstoffalternativen gegenübergestellt. Keine der Alternativen erfüllt alle Kriterien der Bewertung. Bei einer möglichen Werkstoffsubstitution sehen wir insbesondere den Verlust der Sicherheit in der Anwendung als größtes Risiko. Es ist jedoch nicht auszuschliessen, dass zukünftig neue Technologien entwickelt werden, die einen geringeren Bedarfen Fluorpolymeren aufweisen werden. Deshalb könnte zu einem späteren Zeitpunkt eine erneute Überprüfung erfolgen (nach mehr als 15 Jahren). |
| Answer to specific info request 8:  Die sozioökonomischen Auswirkungen der Produkte der Firma wurden untersucht, für Prelon und für die Summe aller Kunden. Die Details sind in der Anlage beigefügt. |

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| 4600 | Date:  2023/06/19 14:36  Content:  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  SABIC Petrochemicals B.V.  Org. country:  Netherlands  Attachment:    <redacted> | General Comments:  PVDF-HFP [Poly(vinylidene fluoride-co-hexafluoropropylene)] is used as processing aids for manufacturing of metallocene linear low density polyethylene (mLLDPE) granules, including LLDPE films for packaging applications. |
| Answer to specific info request 6:  PVDF-HFP [Poly(vinylidene fluoride-co-hexafluoropropylene)] is used as processing aids for manufacturing of metallocene linear low density polyethylene (mLLDPE) granules, including LLDPE films for packaging applications. Supporting documents can be found in Annex IV (Non-Confidential) and Annex V (Confidential). |

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| 4601 | Date:  2023/06/19 14:44  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Federation of the European Cookware, Cutlery and Housewares Industries (FEC)  Org. country:  France  Attachment: | General Comments:  The members of FEC, the Federation of the European Cookware, Cutlery and Housewares Industries, recognize the adverse effects on the environment and human health caused by certain chemicals within the PFAS family, but are concerned by an approach which universally restricts all PFAS without any distinction between the many different types, properties, and risk levels and without considering the greater impacts on European competitiveness and strategic autonomy. The Restriction Proposal should take into consideration the difference in risk and exposure between polymeric and non-polymeric PFAS and the absence of environmental risk from the cookware and bakeware sectors during the production, use, and end of life phase. Based on these grounds, FEC recommends excluding the use of fluoropolymers for cookware and bakeware from the scope of restriction.  Please see the attached documents for more details and information. An independent economic impact assessment will be submitted by FEC in a second contribution before September 2023.  1) There are critical differences between polymeric and non-polymeric PFAS, something already accounted for by the restriction dossier. Fluoropolymers have been thoroughly studied for decades and are among the most well-understood groups of substances classified as PFAS under the OECD definition. Unlike non-polymeric PFAS, which are mobile, can bioaccumulate, and can have toxicity concerns, fluoropolymers have not been demonstrated to have negative health concerns and are a material of choice for sensitive applications such as medical devices, demonstrating strong confidence in their safety. (References in Section 1 of non-confidential attachment)   2) The production of fluoropolymer-coated cookware does not result in significant PFAS emissions into the environment due to the minimal content of non-polymeric PFAS in raw materials and effective environmental management measures. Additionally, non-fluorinated polymerisation aid technologies have the potential to greatly reduce the use of non-polymeric PFAS in the production process. (References in Section 2 of non-confidential attachment)   3) Fluoropolymers from food contact applications are unlikely to result in significant environmental emissions during the end-of-life phase. Landfilling, which represents a shrinking share of total EU waste management, is an unlikely source of PFAS emissions from fluoropolymers, due to the stability of the substances and lack of high ambient temperatures. Recycling and incineration, using adapted BATs that take into account PFAS control, result in full mineralisation of fluoropolymers, thereby preventing any degradation into non-polymeric PFAS. (References in Section 3 of non-confidential attachment)   4) Consequently, the members of FEC consider that the universal restriction proposal lacks proportionality, regarding the absence of environmental risk from the cookware and bakeware sectors during production and end of life phase, and the difference in risk and exposure between polymeric and non-polymeric PFAS. All PFAS should not be grouped together because of their diverse properties. Fluoropolymers are inert, not water soluble and not mobile in the environment, their high molecular weight makes them non bio available and non-bioaccumulative. Besides, persistency alone is not a hazard criterion according to REACH and CLP.  By comparison, the United Kingdom have also proposed Regulatory Management Options for PFAS and suggest a restriction excluding fluoropolymers: “The restriction(s) set out above need not apply to low hazard groups or low risk uses, for example; fluoroplastics or fluoroelastomers (low hazard groups) […]. These could be highlighted as derogations to any restriction proposal.” [https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf]. Based on these grounds, FEC recommends excluding the use of fluoropolymers for cookware and bakeware from the scope of restriction.  5) The cookware and bakeware industries widely use fluoropolymers due to their unique combination of properties (e.g. non-stick, high temperature resistance, durability, heat conductivity, and resistance to abrasion). Ceramic cookware, the only credible non-stick alternative, has lower non-stick durability and performance, requiring more frequent replacement with an increased environmental impact. There is no guarantee that, even with R&D investment and sufficient transition timing, alternatives can be found without compromising the high performance, durability, and functionality which are essential to maintain European competitiveness over Asia. (References in Section 4 of non-confidential attachment)   6) Any fluoropolymer restriction for the cookware and bakeware industries would have consequences on European strategic autonomy, competitiveness, and employment. The PFAS restriction proposal, as it is currently framed, would lead some parts of the industry to abandon their European production (fluoropolymer-coated cookware production for export markets; most R&D centres).   Even if a realistic delay of 12 years were to be granted (the minimum estimated by the sector to complete all the transformation steps), some parts of the industry would not be able to absorb reconstruction costs of roller coating lines into spray lines necessary to produce ceramic, resulting in the collapse of major actors. European manufacturers that are able to bear the transformation costs and R&D costs will encounter a lack of competitiveness, due to investments to transform factories being comparatively lower in Asia. Finally, the significant investments will result in higher prices for consumers when purchasing cookware, and consumers may choose to buy cheaper imported products from outside Europe. (Reference in Section 5 of non-confidential attachment)   7) Consequently, the universal restriction proposal is not proportional to the economic risks associated. Even if a 12-year derogation were granted, only the most resilient European producers will be able to continue manufacturing in Europe, while others will have to close their facilities or offshore them.  8) With the minimal risks presented by fluoropolymer-coated cookware and bakeware, the economic disruption is disproportionate to the gains in protection afforded to EU citizens. Therefore, FEC requests the exclusion of fluoropolymers from the scope of restriction for use in cookware and bakeware. |
| Answer to specific info request 1:  The comments apply to the sectors of cookware and bakeware that make use of fluoropolymer based non-stick coatings. Annex XV identifies the corresponding uses for such coatings, which encompass domestic use as well as use in the kitchens of restaurants and hotels (“Consumer Cookware” in Table 9 in the Annex XV restriction report). |
| Answer to specific info request 2:  Further data relevant to this question will be submitted at a later date as part of a second set of information from FEC. 1) Baseline: Annual tonnage of fluoropolymers used for cookware and bakeware applications in Europe were estimated by the Fluoropolymer Product Group of Plastics Europe at:  - 2 000 tonnes in 2020 (the overall fluoropolymer market in Europe representing a total of 40 000 tonnes in 2020). [https://fluoropolymers.plasticseurope.org/application/files/1216/5485/3500/Fluoropolymers\_Market\_Data\_Update\_-\_Final\_report\_-\_May\_2022.pdf] - 3 500 tonnes in 2015 (the overall fluoropolymer market in Europe representing a total of 52 000 tonnes in 2015) [https://fluoropolymers.plasticseurope.org/application/files/7816/1167/4026/Final\_SEA\_Fluoropolymers\_summary2017\_3.pdf] 2) In the manufacturing phase of cookware and bakeware, the production of fluoropolymer-coated cookware does not result in relevant PFAS emissions into the environment due to limited content of non-polymeric PFAS in raw materials (below 1 ppm) and effective environmental management measures: - 3500 t of fluoropolymers were used in 2015 in Europe (2000 tons in 2020). Typically, the level of residual primary non-polymeric PFAS in the fluoropolymer dispersion is lower than 1ppm (see below). This is the residual level of the fluorinated polymerisation aid used by the fluoropolymer manufacturer. - Therefore, less than 3,5 kg of non-polymeric PFAS are contained in raw materials used overall in Europe by coating manufacturers each year for cookware and bakeware applications. Consequently, banning the use of fluoropolymers for cookware would only potentially remove 3,5 kg of non-polymeric PFAS throughout Europe, while having an extreme negative impact on the sector.  - Fluoropolymer manufacturers have mentioned in their Risk Management Option Analysis that abatement and recovery technologies are widely used in their industry leading to significant reduction in residual primary non-polymeric PFAS. The figure of 1 ppm residual is a common accepted figure in the sector, more details can be obtained directly from polymer manufacturers on a confidential basis.  - “The recovery/recycling techniques have been applied since the beginning of the 1990s and at the present time, they are installed in many FPs manufacturing facilities around the world and used for a variety of polymerisation aids. Recapture rate for fluorinated polymerisation aids of approximately 98% is achieved by some companies.” [https://fluoropolymers.plasticseurope.org/application/files/5416/5104/8333/20211104\_FP\_RMOA\_Final\_3.pdf] 3) In the end-of life phase: Fluoropolymers from food contact applications are unlikely to result in significant environmental emissions: a) Recycling and incineration, using adapted BATs that take into account PFAS control, result in full mineralisation of fluoropolymers, thereby preventing any degradation into non-polymeric PFAS: - It is assumed that 3500 tons of fluoropolymers are contained in cookware and bakeware used every year in Europe.  - The first stage of treatment by incineration at 600°C in the presence of calcium hydroxide leads to 90% abatement of fluoropolymers according to Fei Wang et al [Fei Wang et al., Environ. Sci. Technol. 2015, 49, 5672−5680]   - Further treatments at 1 150 °C lead to 99.9999% decomposition of fluoropolymer according to the “Report on PFAS Destruction Testing Results at Clean Harbors’ Aragonite, Utah Hazardous Waste Incinerator”.   - Typically, afterburners are used generally under those operating conditions to convert unburned VOC to CO2 and H2O (according to the US EPA, most afterburner at the moment in the US are operating between 980°C to 1 200°C to eliminate VOC). [https://www3.epa.gov/ttncatc1/dir1/fthermal.pdf]  - This lead to below 1 kg per year of PFAS emission, from recycling and incineration, per year at EU level, if best available technologies are utilized during the recycling and incineration process and collection schemes are more widely used.  b) Landfilling, which represents a shrinking share of total EU waste management, is an unlikely source of PFAS emissions from fluoropolymers, due to the stability of the substances and lack of high ambient temperatures: - Emissions from fluoropolymers coated cookware in landfill is expected to be insignificant, according to various authorities and authors, including RIVM [https://www.rivm.nl/bibliotheek/rapporten/2021-0143.pdf] and the ITRC [https://pfas-1.itrcweb.org/2-1-environmental-significance]. The Waste Framework Directive sets a maximum total of 10% of waste going to landfill by 2035, and many member states already have landfilling rates substantially below this figure, further minimizing potential emissions during landfilling.  4) In the consumer use phase: it can be assumed that there are no emissions of fluorinated polymerisation aids because the traces of fluorinated polymerisation aids (< 1 ppm) from polymer production are successfully removed from the coating during the firing process, as confirmed by EFSA:   - In its 2011 scientific opinion regarding the use of the fluorinated polymerisation aid 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid], ammonium salt (ADONA, CAS 958445-44-8), the European Food Safety Authority notes that : “It is (…) expected that the decomposition products as well as the substance itself are efficiently removed from the polymer during thermal processing (high temperature extrusion, baking or sintering) into a final article.” The authority also reported content analyses on four different materials and noted that “in all [four] cases the substance was not detectable in the final sintered perfluoropolymer materials at a detection limit of 0.02 mg/kg.” [EFSA Journal 2011; 9(6):2182 ] - Similarly for the substance perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt (CAS 908020-52-0), EFSA noted that “it can (…) be expected that any post-polymerisation residual content of the substance is efficiently removed during thermal processing (high temperature extrusion, baking or sintering) into a final article. This was supported by an analytical screening experiment on a finished food contact PTFE polymer.” Following a set of migration testing, they also conclude that “the data indicate that final PTFE food contact polymers do not contain the substance at concentrations which cause measurable migration into foods.” [EFSA Journal 2011; 9(6):2183] - The German BfR commented in 2022 that there is no risk for consumers when using cookware with a non-stick coating. This was confirmed by a survey by FEC on products from the European market also showed no exposure of consumer to non-polymer [https://mobil.bfr.bund.de/cm/349/selected-questions-and-answers-on-cookware-ovenware-and-frying-pans-with-a-non-stick-coating-made-of-ptfe.pdf] - A survey from Choi et al in 2018 [Choi, Heeju, In-Ae Bae, Jae Chun Choi, Se-Jong Park, and MeeKyung Kim. 2018. “Perfluorinated Compounds in Food Simulants after Migration from Fluorocarbon Resin-Coated Frying Pans, Baking Utensils, and Non-Stick Baking Papers on the Korean Market.” Food Additives & Contaminants: Part B 11 (4): 264–72] also confirmed that in the vast majority of products from the Korean market did not release non-polymeric PFAS when tested. A small minority of products showed detectable PFAS and even in this case, the authors only detected PFAS in the first migration. |
| Answer to specific info request 3:  According to the dossier submitters, the assumed potential for emissions of non-polymeric PFAS from fluoropolymers is overwhelmingly accounted for in the end-of-life stage (shown in Figure B.69 in Annex XV report)). Fluoropolymers from food contact applications can be adequately addressed in the waste stream. The following studies represent the state-of-the-art scientific knowledge on the question of fluoropolymer fate during incineration. The conditions in incineration can be met to ensure full mineralisation of fluoropolymers after incineration:  - Fluoropolymers, including PTFE, are completely destroyed under specific incinerator operating conditions: Yamada et al studied textiles and paper treated with fluorotelomers at temperatures of 1 000°C and residual times of 2 seconds. They found that they will be destroyed and will not be a source of PFOA in the environment. [Yamada, Takahiro, Philip H. Taylor, Robert C. Buck, Mary A. Kaiser, and Robert J. Giraud. 2005. “Thermal Degradation of Fluorotelomer Treated Articles and Related Materials.” Chemosphere 61 (7): 974–84]  - According to a 2019 study from the Karlsruhe Institute of Technology, municipal incineration of PTFE did not result in significant generation of studied PFAS at temperatures between 870 and 1 020 °C. Instead, the PFAS degraded mainly into hydrofluoric acid and carbon dioxide. [Aleksandrov, Krasimir, Hans-Joachim Gehrmann, Manuela Hauser, Hartmut Mätzing, Daniel Pigeon, Dieter Stapf, and Manuela Wexler. 2019. “Waste Incineration of Polytetrafluoroethylene (PTFE) to Evaluate Potential Formation of Per- and Poly-Fluorinated Alkyl Substances (PFAS) in Flue Gas.” Chemosphere 226 (July): 898–906]  - According to a 2021 report by the Dutch RIVM, PTFE is reduced to a fully mineralized state after 2 seconds of incineration at 850°C. Incinerator bed temperatures, which generally range between 900 and 1 100°C, PTFE and other fluorinated polymers are expected to fully degrade into small fluorocarbon molecules. For a high degree of thermal degradation, temperatures higher than 850 °C are required. [Bakker, J., B. Bokkers, and M. Broekman. 2021. “Per- and Polyfluorinated Substances in Waste Incinerator Flue Gases.” Rijksinstituut voor Volksgezondheid en Milieu RIVM. December 8, 2021]  - In 2021, an independent study of PFAS in hazardous waste incineration in Utah showed a thermal destruction of more than 99.9999 % at temperatures of 1 154°C. [Quinn, Megan. 2023. “Clean Harbors Says It Can Destroy More than 99% of PFAS at Incinerator Facility.” Waste Dive. January 23, 2023. https://www.wastedive.com/news/clean-harbors-incinerator-pfas-forever-chemicals/640829/]  - In the JRC Science Report to the European Commission on the “Best Available Technology (BAT) Reference Document for the Non-Ferrous Metals Industries”, it is recommended to use absorbents such as calcium hydroxide to remove gaseous components [Cusano, Gianluca, Miguel Rodrigo Gonzalo, Frank Farrell, Rainer Remus, Serge Roudier and Luis Delgado Sancho. 2017. “Best Available Techniques (BAT) Reference Document for the Non-Ferrous Metals Industries: Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control)”. 2017.].   - Fei Wang et al. showed that the mineralisation ratio of polytetrafluoroethylene (PTFE) particles by calcium hydroxide could reach 80% or higher when the temperature was above 400 °C [Wang, Fei, Xingwen Lu, Xiao-yan Li, and Kaimin Shih. 2015. “Effectiveness and Mechanisms of Defluorination of Perfluorinated Alkyl Substances by Calcium Compounds during Waste Thermal Treatment.” Environmental Science & Technology 49 (9): 5672–80] From this set of literature data, there seems to be a set of parameters that allow full mineralisation of fluoropolymers by using a combination of incinerators, filter systems and afterburners even in the municipal waste stream. |
| Answer to specific info request 8:  With the minimal risks presented by fluoropolymer-coated cookware (see sections 1, 2, 3 in non-confidential attachment), the economic disruption and effects on European competitiveness and autonomy would be disproportionate to the gains in protection afforded to EU citizens. FEC requests the exclusion of fluoropolymers from the scope of restriction for use in cookware and bakeware.  1) The PFAS restriction proposal, as it is currently framed, would have significant economic and social impacts on the bakeware and cookware industry, leading to the potential cessation of important parts of the business:  - Substantial investments would be necessary to rebuild or adjust the industrial processes of cookware manufacturers to switch to alternatives. Production of ceramic coatings is not compatible with roller coating technology, covering at present a significant portion of European cookware production. The transformation of roller coating lines will incur substantial costs and will result in immediate write-offs of investments into these production lines. Even when already using spray technology to produce fluoropolymer coated cookware, manufacturers will have to invest to adapt their production lines to transition to alternatives. - Significant investments in R&D would be required for exploration and development of alternative options: to find performant and cost competitive alternatives to fluoropolymers, to diversify product offerings, to prevent loss of competitiveness, revenue, and to maintain brand reputations. - Some parts of the industry will have to cease their production automatically and irreversibly (European production destined to export markets, which is a significant part of European cookware production, as well as R&D centres for fluoropolymer coatings). Some companies, especially SMEs, will not be able to absorb the costs of transition (reconstruction of roller coating lines not compatible with ceramic production). Other European manufacturers will face high transformation costs and R&D costs, undermining their effort to stay competitive over Asian production. - Job losses in Europe will be permanent, as the loss of industrial structure and know-how would make any re-industrialisation plan in Europe nearly impossible, particularly if market share is lost to cheaper non-EU producers.   - The transition will be difficult because of shortages in the supply chain. The R&D intensive transition will be limited by an overload in the R&D departments of coating manufacturers. The cookware industry shares raw material suppliers with other high-volume industries, which poses the risk of significant delays and additional costs due to lower volumes or the prioritisation of other products. New machinery and spare parts of existing machinery would need to fulfil potential future ECHA restrictions on PFAS. There are a significant uncertainty and potential bottlenecks in acquisition of new and repair of existing production equipment. The demand in raw material and spare parts to build and adapt production lines will probably increase at the same time, with a risk of shortages. - The proposal has several negative impacts for the consumer. The massive investments in rebuilding and/or adapting lines will increase the cost of the final cookware or bakeware article for the consumer. The alternative for the consumer would be to buy cheaper cookware and bakeware imported from outside of Europe. The shorter lifespan of ceramic coating in comparison to PTFE coating as well as the lower productivity of spray (compared to roller coating), will generate uncertainty for European manufacturer capacity to adapt rapidly to the growing demand. The consumer will lose access to fluoropolymer coated bakeware and cookware, offering a unique mix of key properties such as durability of non-stick, product durability, thermal resistance, ease of cleaning, corrosion resistance, chemical resistance.  2) The most realistic transition time estimated by the cookware and bakeware sector to complete all the transformation steps would be 12 years, with very high economic risk, risk of failure and risk for employment: - R&D, coating development: 2 years (to adapt the existing technology) to 5 years to get a breakthrough with a product as performant as fluoropolymers (with a high risk of failure in this research). Most companies would like to differentiate their product and adapt the existing technology, with heavy investments in R&D and in production lines. Even for companies that are willing to use existing technology (and that would not need to go through R&D steps to adapt the existing technology), they would still have to change their industrial structure, with heavy investments and long delays. - R&D, technology development: 3-5 years to deliver and economically viable process  - Product offer: 2-3 years  - Production line replacement (Ordering machinery; installation): 1-2 years but replacement one line at a time to avoid stopping the production process (i.e. 5 years if the company has 5 lines)  - Local authorities’ approval: 1 year  - Staff training and safety measures (in parallel): 6 months in parallel with production line replacement  - Commercial deployment in different markets (Product adaptation, product stock clearance, change merchandising): 2-3 years  3) Given the high economic risks associated with the restriction, even in the case of a transition time of 12 years, the bakeware and cookware sectors request the exclusion of fluoropolymers from the scope of restriction for use in cookware and bakeware:   - Transformation costs will be too high to be bearable for some European companies, particularly SMEs or smaller firms, resulting in the inability to continue business for these companies. - Transformation of lines and investments in R&D will eventually be absorbed by the most resilient companies, but costs will be significantly lower in Asia than in Europe, undermining the effort of European producers to stay competitive over Asia, and incentivising offshoring. - There is no guarantee that suitable alternatives can be found without compromising crucial factors such as high performance, durability, and functionality. These qualities are vital for European producers to maintain their competitive advantage and their industry presence in Europe. - Fluoropolymers have not been demonstrated to have negative health concerns and their use by the cookware and bakeware industries is unlikely to result in significant environmental emissions during the manufacturing, use and end-of-life phases (cf sections 1-3).   - The restriction is not proportional to the economic risks. Even if a 12-year derogation were granted, only the most resilient European producers will be able to continue manufacturing in Europe, while others will have to close their facilities or offshore them. With the minimal risks presented by fluoropolymer-coated cookware, the economic disruption is disproportionate to the gains in protection afforded to EU citizens. |

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| 4602 | Date:  2023/06/19 14:58  Content:  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  GEA Mechanical Equipment Italia S.p.A.  Org. country:  Italy  Attachment:  <redacted> | General Comments:  For technical reasons we cannot do without the materials FKM, FFKM and PTFE. Without these materials many of our machines can’t be operated in the market anymore and also not be sold further on. Our machines are installed in many key industries worldwide. These industries include pharmaceutical & biotech applications, chemical applications, dairy applications, beverage applications and many other similar industries. |
| Answer to specific info request 6:  Please see the annex |
| Answer to specific info request 7:  Please see the annex |
| Answer to specific info request 8:  Please see the annex |

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| 4603 | Date:  2023/06/19 16:44  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 1:  Construction products (Annex E.2.13.): PTFE thread sealing tape 1. It is widely used in gas industry as a protection of the connection between cylinder valve and cylinder. This is an essential functionality of PTFE tape as it provides lubrication of the thread, guarantee disassembly of the valve when necessary. Easy application and reliable performance in this application is not easy to replace. Historically used solution with cones based on silver and lead (alternatively including tin or aluminum) are not acceptable as they also contain problematic material. Gas companies run millions of cylinders globally and PTFE tape is used on almost every of these cylinders. If there is other solution like PTFE cones or PFPE based liquid lubricant, it is still based on PFAS. We need further information from suppliers and development work with them to estimate the derogation period that we would need. 2. PTFE thread sealing tape is also used in equipment for cryogenic and low temperature service. In this use we do not see any alternatives available yet and not under study. 3. PTFE thread sealing tape is used also in many other connections of gas production equipment where different design approach will need to be implemented to eliminate the use of PTFE. This will require time and investment into new equipment. Availability of spare parts including PTFE tape will be essential for maintenance until the new equipment is available. We need further information from suppliers and development work with them to estimate the derogation period that we would need. Lubricants (Annex E.2.14.): Sector as whole We appreciate that lubricants are selected in the group with 13,5 years derogation which highlights specifics characteristics of this products. PFPE based lubricants are widely used in gas equipment for great resistance in oxidizing atmosphere and high pressure. Introduction of these lubricants significantly reduced occurrence of oxygen ignitions (fire) and improved safety of our employees, customers and patients. The applied quantities of the lubricant during manufacturing are very small and there is a high level of control for quantity applied to each piece of equipment to ensure functionality but not overdose lubricants. Currently we see no evidence of availability for alternative guaranteeing adequate level of safety and expectation of successful development of such alternative is on very low probability within the proposed derogation time. |

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| 4604 | Date:  2023/06/19 21:17  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  W. L. Gore & Associates GmbH  Org. country:  Germany  Attachment:    <redacted>  Privacy statement:  As disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property (Article 4(2) of Reg. (EC) No 1049/2001). | General Comments:  See Attachments |
| Answer to specific info request 1:  Medical Devices |
| Answer to specific info request 6:  Medical Devices |