**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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| 5971 | Date:  2023/06/29 17:48  Type:  BehalfOfAnOrganisation  Org. type:  National NGO  Org. name:  Svenska naturskyddsföreningen  Org. country:  Sweden  Privacy statement:  - | General Comments:  Time to prohibit PFAS! |

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| 5972 | Date:  2023/06/29 18:07  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  Individual  Country:  Sweden | General Comments:  Jag tycker att begränsningsförslaget är bra som det är och hoppas att det inte kommer urvattnas. För mig är det extremt viktigt att vi stoppar långlivade kemikalier, och inte alls lika viktigt att produkterna som tillverkas är lite bättre. Om PFAS slutar användas är det en vinst även om regnjackan blir lite mindre vattentät eller mobilen lite större. |

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| 5973 | Date:  2023/06/29 18:31  Content:  Scope or restriction option analysis  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  General Gas S.r.l.  Org. country:  Italy | General Comments:  - |
| Answer to specific info request 1:  Applications of fluorinated gases: Refrigeration, Air conditioning, Heat Pump |
| Answer to specific info request 2:  Applications of fluorinated gases in the use phase: Refrigeration: the application of refrigeration can be organized in the following sections: 1 - Plug-in commercial refrigeration systems > The emission of fluorinated refrigerant is under 0,5% of the charge per year during the life of appliances. 2 - Non Plug-in commercial refrigeration systems > The emission of fluorinated refrigerant is drastically decreasing year per year because of the controls requested by F-Gas Regulation. In 2022 we can estimate the medium emission equal to 8% of the charge per year , decreasing at least 1% every 2 years. 3 - Non Plug-in industrial refrigeration systems > The emission of fluorinated refrigerant is drastically decreasing year per year because of the controls requested by F-Gas Regulation. In 2022 we can estimate the medium emission equal to 4% of the charge per year , decreasing at least 1% every 3 years. Air Conditioning & Heat Pump ( AC & HP ) in the use phase: 1 - Plug-in AC&HP systems > The emission of fluorinated refrigerant is under 0,5% of the charge per year during the life of appliances. 2 - Non Plug-in AC&HP systems > The emission of fluorinated refrigerant is drastically decreasing year per year because of the controls requested by F-Gas Regulation. In 2022 we can estimate the medium emission equal to 4% of the charge per year , decreasing at least 1% every 2 years. Both Refrigeration Systems and Air Conditioning / Heat Pump are wasted as appliances in RAE center, recovering the refrigerant contained in the appliances. In this end of life phase a good estimation of the medium recovery ratio can be 90% of the refrigerant contained in the systems. All the RAE center are working to improve the efficiency of the recover process increasing the recovery ratio. If the system is not easily transported in RAE center, they are evacuated by contractor using recovery machine and vacuum pump used in the field. In this case 98% of the refrigerant is recovered and recycled using some portable recycling machine ( 80% ) or sent to reclaim center made of company authorized for the reclaiming of the refrigerant ( 20% ). All these value are well estimated inside our industrial association exchanging information also with the Italian association of contractors. |
| Answer to specific info request 4:  I have information on the hypothesis that it will be necessary to reclaim the recovered refrigerant discharged from systems that must be wasted. To reclaim the recovered refrigerant from the system at end of life of them or under the necessity to waste the same system, it is necessary to have the availability of the contractors in wasting the system and recover the refrigerant + the availability of the reclaiming facility or incineration site + the availability of the contractors to install the new systems not using fluorinated refrigerant ( CO2 and R290 in refrigeration equipment + R290 in air conditioning and heat pump ). We remember that the R290 systems require qualified contractors that are able to install and maintenance the system. The number of contractors that have this know how is actually less than 1% of the total number. Discussing with the association of the contractors, they affirm that it is necessary to have the time to certify a sufficient number of contractors to avoid to use refrigeration and air conditioning systems that can cause very dangerous incident with the risk of hundred of death. So al we know that the capacity of reclaiming or the capacity of incineration of the recovered refrigerant could be increased in 3/5 years, but the whole process that require the wasting of the refrigeration and air conditioning systems require at least 15/20 years to be completed guaranteeing a safe use of the R290 equipment or systems. A different consideration must be done to waste the refrigeration system working with fluorinated refrigerant with CO2 system. The critical issue is the energy efficiency of the refrigeration equipment working with CO2; it is much lower if compared vs the energy efficiency of systems working with HFO refrigerant ( -25%/-35% ) generating and increase of the electricity used by the systems working with CO2 ( +25% / +35% if compared vs the systems working with fluorinated refrigerants ). The operating cost of the CO2 system are much more higher that the operating cost of the equipment working with HFO. Also the CO2 emitted in atmosphere is 25%/35/ more compared with the technology using HFO ); so the adoption of the CO2 technology will produce much more CO2 emitted in the atmosfere. Also in this case it is necessary time for the industries to find the way to increase the energy efficiency of CO2 refrigeration system with acceptable cost. we think that 15/20 years could give the possibility to the industries to find the right solutions to guarantee good energy efficiency. |
| Answer to specific info request 5:  There are 2 main application of fluorinated refrigerant that should be derogated: A - All the time the flammability and explosively of R290 ( or other hydrocarbon ) produce a risk that is too high to be managed. For example: A.1 - Air Conditioning systems in school, hospital, public space, houses, public transportation, exhibition centers where the charge of R290 or hydrocarbon is more than 1 kg > A charge equal to 1 kg has an explosion capacity that can generate many death > This application use in Italy roughly 1'000 ton of refrigerant; in many cases the refrigerant used could be R1234ze or blend of it that do not have PBT characteristics as the other substances and that are not flammable ( NOT explosive ) or as happen for R1234ze has very low flammability with NO risk of explosion. A2 -Refrigeration systems in supermarket, cold rooms and production equipment where the charge of R290 or hydrocarbon is more than 1 kg > A charge equal to 1 kg has an explosion capacity that can generate many death > This application use in Italy roughly 800 ton of refrigerant; in many cases the refrigerant used could be blends of R1234ze and R32 ; R32 is not PFAS substance; R1234ze do not have PBT characteristics as the other substances. Both are A2L with very low flammability with NO risk of explosion. There are also some blends of R1234ze that are NOT flammable and not explosive. For the same application using these products it could be possible to avoid the use of CO2 systems avoiding the increase of +25%/+35% of electricity used and of CO2 emitted in the atmosfere. |

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| 5974 | Date:  2023/06/29 20:30  Content:  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Gottlob Dietz GmbH  Org. country:  Germany | General Comments:  The PFAS regulation covers about 10.000 substances. Only approximately 50 substances of these are Fluoropolymers and Fluoroelastomers. Fluoropolymers and Fluoroelastomers can be classified as PFAS based on their molecular structure. However, their toxicological and eco-toxicological profile is essentially different from the majority of PFAS substances. Fluoropolymers and Fluoroelastomers are recognised by the OECD as safe materials: "PLC" = polymer of low concern. They are non-toxic, non-bioavailable, non-water soluble and non-mobile molecules and are judged to have no significant impact on the environment and humans. They do not generate microplastics. For further details see studies of: pro-K Industrieverband Halbzeuge und Konsumprodukte aus Kunststoff e.V. Mainzer Landstraße 55 60329 Frankfurt am Main or The European Chemical Industry Council, AISBL Belliard, 40 - 1040 Brussels – Belgium  We produce products – mainly diaphragms - made of Fluoropolymers (mainly PTFE but PFA and ECTFE as well) and Fluoroelastomers (FKM and FFKM). These products are used in the production process of pharmaceuticals (including vaccines), semiconductors, photovoltaic cells, food and beverages, chemicals, in the water processing and many other industrial applications. In many of these applications the products have to meet the requirements of the FDA, the USP class IV, drinking water requirements and others. There are toxicological tests performed as well as leachability tests for these standards. There does not exist a viable alternative to these materials in these applications. Fluoropolymers and Fluoroelastomers are very expensive and therefore they are already without any ban only used, if no other alternatives are available.  For our products the essential properties of the used Fluoropolymers and Fluoroelastomers are: a) High flexibility (for the movement of diaphragms in pumps, valves and pressure regulators) b) Chemical inertness regarding a big variety of medias, including harsh chemicals like chlorine gas, hydrofluoric acid and others c) thermal resistance against low and high temperatures (higher than 150°C) d) resistance against steam for sterilization in steam e) good cleanability, to avoid contaminations between production batches and growth of bacterias These properties are all necessary within one product. There is no alternative material available, that combines all these properties.  We did check alternatives with the following result: Substitution by other elastomers, for example EPDM: = not suitable a) flexibility: better than now b) chemical inertness: restricted c) thermal resistance: lower (not sufficient) d) resistance against steam: possible up to approximately 120°C, needed up to 145°C (not sufficient) e) cleanability: worse = not suitable  Substitution by other elastomers, for example Silicone: = not suitable a) flexibility: better than now b) chemical inertness: restricted c) thermal resistance: sufficient d) resistance against steam: not suitable e) cleanability: worse Silicone is not firm enough that the parts keep their form during operation = not suitable  Substitution by PEEK: = not suitable a) flexibility: not existing b) chemical inertness: equivalent c) thermal resistance: equivalent d) resistance against steam: equivalent e) cleanability: equivalent = not suitable  Substitution by UHMW-PE: = not suitable a) flexibility: equivalent b) chemical inertness: restricted, problems with highly oxidizing acids (for example nitric acid, chromic acid, or halogens) c) thermal resistance: significantly lower – not usable for our needs d) resistance against steam: not given e) cleanability: equivalent = not suitable  For some uses the theoretically suitable substitutes are much more harmful than Fluoropolymers. For example former asbesto seals had been substituted by PTFE-seals.  Duration of the transition to replacement materials: There is no replacement material available, so it will need an unforeseeable number of years for the research and development for such a material (if something can be developed). After a suitable alternative would be available, the validation in the pharmaceutical industry takes several years. In 2015 we had to substitute an EPDM compound for pharmaceutical applications by another EPDM compound that already existed and was available at that time. Caused by the long and demanding tests this transition took more than 6 years till 2021 for a product for which the alternative was already known. The transition to a product that still has to be developed and tested thoroughly might take far longer than 12 years.  Without Fluoropolymers and Fluoroelastomers a vast range of industries would not be able to produce in Europe any more. For many of these industries, it is the declared goal of the EU to establish them here or strengthen the existing companies, like the pharmaceutical industry, semiconductor production, renewable energies….. Production facilities for the transport of fluids could not be operated in Europe anymore. Numerous medicines, vaccines, chemicals, foods, beverages, semiconductors, photovoltaic cells… could only be produced outside of Europe and so Europe would get dependent on the import of these strategic products from outside Europe. The supply situation would be threatened much more and for a much longer time than during Corona times and it would effect a much bigger range of products. I don’t think that Europe can afford to get under such a strong dependency from other regions.  Even ecological and health reasons recommend to exempt the Fluoropolymers and Fluoroelastomers from the PFAS regulation. It is sure that these raw materials will be needed and used in future, this will just be transferred to other countries outside of the EU. Nowhere else in the world the production, processing and usage of Fluoropolymers is so well regulated, clean and reliable and monitored by ecological standards than in Europe. A relocation of the production, processing and usage to other countries would give up these achievements and could lead to ecological and health threads in other regions of the world.  Based on the recognition by the OECD as safe materials: "PLC" = polymer of low concern we request to exempt the Fluoropolymers and Fluoroelastomers from PFAS regulation or use restrictions. |
| Answer to specific info request 1:  Industrial. Production of products made of Fluoropolymers and Fluoroelastomers. These products are used in the production process of pharmaceuticals (including vaccines), semiconductors, photovoltaic cells, food and beverages, chemicals, in the water processing and many other industrial applications |

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| 5975 | Date:  2023/06/29 20:57  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  Individual  Country:  Sweden | General Comments:  jag tycker att begrensningsförslaget är bra som det är och bör ej utvattnas. |

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| 5976 | Date:  2023/06/29 20:57  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  Individual  Country:  Sweden | General Comments:  Jag tycker att begränsningsförslag är bra som det är och bör ej urvattnas. |

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| 5977 | Date:  2023/06/29 21:41  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  Protection of commercial interests and know-how. | General Comments:  Please see two attachments (one non-confidential and one confidential). |
| Answer to specific info request 6:  Please see two attachments (one non-confidential and one confidential). |

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| 5978 | Date:  2023/06/29 21:47  Type:  Individual  Country:  Denmark | General Comments:  I am an assistant professor at University of Southern Denmark, and in the past 10 years I have studied PFAS health effects in humans with a particular focus on child and maternal health. I am writing to express my support for the proposed EU PFAS restrictions. PFAS are highly persistent chemicals accumulating in our bodies. Due to the global pollution, we now all have PFAS in our bodies, and these chemicals are transferred from mother to child through the placenta during pregnancy and through breastfeeding [1-5] putting infants at high exposure [6, 7]. In addition, infants are particular sensitive to the immunotoxic effects of PFAS [8-10], and we therefore have to do everything in our power to protect infants and their mothers from PFAS. I therefore support stopping all unessential uses of PFAS as soon as possible. While time-limited derogations may be necessary for certain PFAS applications, it is important to motivate the development of safer alternatives so that exposure to all PFAS is minimized.  Best regards, Amalie Timmermann   1. Zheng, P., et al. Prenatal and postnatal exposure to emerging and legacy per-/polyfluoroalkyl substances: Levels and transfer in maternal serum, cord serum, and breast milk. 2022. DOI: 10.1016/j.scitotenv.2021.152446. 2. Mogensen, U.B., et al. Breastfeeding as an Exposure Pathway for Perfluorinated Alkylates. 2015. DOI: 10.1021/acs.est.5b02237. 3. Verner, M.A., et al. A Simple Pharmacokinetic Model of Prenatal and Postnatal Exposure to Perfluoroalkyl Substances (PFASs). 2016. DOI: 10.1021/acs.est.5b04399. 4. Muller, M.H.B., et al. Prenatal exposure to persistent organic pollutants in Northern Tanzania and their distribution between breast milk, maternal blood, placenta and cord blood. 2019. DOI: 10.1016/j.envres.2018.12.026. 5. Criswell, R.L., et al. Concentrations of Per- and Polyfluoroalkyl Substances in Paired Maternal Plasma and Human Milk in the New Hampshire Birth Cohort. 2023. DOI: 10.1021/acs.est.2c05555. 6. Haug, L.S., et al. Characterisation of human exposure pathways to perfluorinated compounds--comparing exposure estimates with biomarkers of exposure. 2011. DOI: 10.1016/j.envint.2011.01.011. 7. Papadopoulou, E., et al. Exposure of Norwegian toddlers to perfluoroalkyl substances (PFAS): The association with breastfeeding and maternal PFAS concentrations. 2016. DOI: https://dx.doi.org/10.1016/j.envint.2016.07.006. 8. Dalsager, L., et al. Exposure to perfluoroalkyl substances during fetal life and hospitalization for infectious disease in childhood: A study among 1,503 children from the Odense Child Cohort. 2021. DOI: 10.1016/j.envint.2021.106395. 9. Timmermann, C.A.G., et al. Concentrations of tetanus and diphtheria antibodies in vaccinated Greenlandic children aged 7-12 years exposed to marine pollutants, a cross sectional study. 2022. DOI: 10.1016/j.envres.2021.111712. 10. Timmermann, C.A.G., et al. Serum Perfluoroalkyl Substances, Vaccine Responses, and Morbidity in a Cohort of Guinea-Bissau Children. 2020. DOI: 10.1289/EHP6517. |

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| 5979 | Date:  2023/06/30 00:04  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  Individual  Country:  Sweden | General Comments:  Begränsningsförslaget är bra som det är jag hoppas innerligt att det inte urvattnas. Det är viktigt att vi helt stoppar utsläpp av långlivade kemikalier. Jag är medveten om att detta kan ge varor sämre egenskaper som mindre regntät jacka eller tyngre mobiltelefon och kan acceptera detta om det innebär att PFAS-användningen stoppas. |

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| 5980 | Date:  2023/06/30 03:33  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Korea, Republic of  Company name confidential:  Yes | General Comments:  We are a manufacturer of Secondary battery parts, especially for high-performance rechargeable Lithium-ion cells and batteries to be used within the for electric vehicle industry for the EU/EEA.  We would like to disagree on the current proposal of the PFAS ban.  We use PFAS-based materials in our production of seal gasket.  Today, this is the only available material to be used to manufacture a seal gasket that can meet up to the specifications of sealing capability, high mechanical reliability and thermal resistance at the same time and it is used to protect heating or cooling systems in electroplating as well.  Please refer to the attached Chemical, Physical, Thermal, Electrical and Mechanical properties, Flammability, Gas and Moisture permeability, Light transmissivity, and Heat aging resistance from our supplier [CONFIDENTIAL].  Those properties of PFAS is extremely outstanding in sealing capability, high mechanical reliability and thermal resistance, currently there is no suitable substitute material.  PFAS is used in the electric motors, rechargeable Lithium-ion batteries of electric cars, and to sensors where PFAS must be used to permanently protect from oils or greases.  Without utility of PFAS, above listed products will malfunction and eventually it will bring injuries for passengers.  Also in medical technology in endoscopic instruments used for operations and new areas of application are added every day, as fluoroplastics have a significantly longer service life compared to conventional plastics, but at the same time are harmless to the body and the environment.  Fluoroplastics such as PTFE, FEP, PFA and the 35 other materials in this group are unfortunately indispensable and irreplaceable due to their valuable properties, so far there is not substitutable material in our business sector.  We are a small medium-sized company that processes PFAS, as well as our customers in automotive and EV battery sectors, will experience significant impairments and will not be able to keep up with competitors from non-EU countries in the long term. Investments, employees and sustainable production facilities will not be paid off and We will lose annual 120 million EUR Annual sale business and our over 259 employees in Poland would lose their job and we be closed due to the resulting those losses ultimately.  Fluoropolymers are classified as PFAS according to the OECD definition, they also meet the OECD polymer of low concern criteria[1] and are by OECD considered safe for human health and the environment, as they are non-toxic, bio-compatible, non-soluble, and immobile. Therefore, fluoroplastics should not be part of this PFAS restriction, as it is necessary to defer the use regulation and conduct a detailed investigation on the future plan and current situation through contact with workers in various fields of use.  [1] OECD, 2006. OECD definition of polymer. OECD Environment, Health and Safety Publications. Available at: https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm    Otherwise the damage to our further development and our economy will be immense.  Again, we ask for the exemption of the PFAS our use.  Thank you for your time. |
| Answer to specific info request 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. • Mechanical components of high performance rechargeable Lithium-ion batteries |
| Answer to specific info request 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: In our Manufacture process, it was named as a special process for the application of PFAS materials, and a separate investment of about 1,100,000 EUR in 2021 was made for a separated space and individual environmental we produce parts made from PFAS-based material in our factory with state of the art technologies under controlled circumstances and continuously measured waste water and air quality with no PFAS emission. |
| Answer to specific info request 3:  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. There are specific requirements for emission levels and combustion conditions (temperature, time slots for duration in high temperature areas..) for incineration plants, which meet requirements for safe destroying PFAS and we are following all the requirement. |
| Answer to specific info request 6:  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: I have information on this topic (Check) Seal gaskets to be used for high-performance rechargeable Lithium-ion batteries applications Many thanks and best regards. |

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| 5981 | Date:  2023/06/30 03:51  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Korea, Republic of  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  We are a manufacturer of Secondary battery parts, especially for high-performance rechargeable Lithium-ion cells and batteries to be used within the for electric vehicle industry for the EU/EEA.  We would like to disagree on the current proposal of the PFAS ban.  We use PFAS-based materials in our production of seal gasket.  Today, this is the only available material to be used to manufacture a seal gasket that can meet up to the specifications of sealing capability, high mechanical reliability and thermal resistance at the same time and it is used to protect heating or cooling systems in electroplating as well.  Please refer to the attached Chemical, Physical, Thermal, Electrical and Mechanical properties, Flammability, Gas and Moisture permeability, Light transmissivity, and Heat aging resistance from our supplier [CONFIDENTIAL].  Those properties of PFAS is extremely outstanding in sealing capability, high mechanical reliability and thermal resistance, currently there is no suitable substitute material.  PFAS is used in the electric motors, rechargeable Lithium-ion batteries of electric cars, and to sensors where PFAS must be used to permanently protect from oils or greases.  Without utility of PFAS, above listed products will malfunction and eventually it will bring injuries for passengers.  Also in medical technology in endoscopic instruments used for operations and new areas of application are added every day, as fluoroplastics have a significantly longer service life compared to conventional plastics, but at the same time are harmless to the body and the environment.  Fluoroplastics such as PTFE, FEP, PFA and the 35 other materials in this group are unfortunately indispensable and irreplaceable due to their valuable properties, so far there is not substitutable material in our business sector.  We are a small medium-sized company that processes PFAS, as well as our customers in automotive and EV battery sectors, will experience significant impairments and will not be able to keep up with competitors from non-EU countries in the long term. Investments, employees and sustainable production facilities will not be paid off and We will lose annual 120 million EUR Annual sale business and our over 259 employees in Poland would lose their job and we be closed due to the resulting those losses ultimately.  Fluoropolymers are classified as PFAS according to the OECD definition, they also meet the OECD polymer of low concern criteria[1] and are by OECD considered safe for human health and the environment, as they are non-toxic, bio-compatible, non-soluble, and immobile. Therefore, fluoroplastics should not be part of this PFAS restriction, as it is necessary to defer the use regulation and conduct a detailed investigation on the future plan and current situation through contact with workers in various fields of use.  [1] OECD, 2006. OECD definition of polymer. OECD Environment, Health and Safety Publications. Available at: https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm    Otherwise the damage to our further development and our economy will be immense.  Again, we ask for the exemption of the PFAS our use.    Thank you for your time. |
| Answer to specific info request 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. • Mechanical components of high performance rechargeable Lithium-ion batteries• |
| Answer to specific info request 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: In our Manufacture process, it was named as a special process for the application of PFAS materials, and a separate investment of about 1,100,000 EUR in 2021 was made for a separated space and individual environmental we produce parts made from PFAS-based material in our factory with state of the art technologies under controlled circumstances and continuously measured waste water and air quality with no PFAS emission. |
| Answer to specific info request 3:  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. There are specific requirements for emission levels and combustion conditions (temperature, time slots for duration in high temperature areas..) for incineration plants, which meet requirements for safe destroying PFAS and we are following all the requirement. |
| Answer to specific info request 6:  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: I have information on this topic (Check) Seal gaskets to be used for high-performance rechargeable Lithium-ion batteries applications Many thanks and best regards. |

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| 5982 | Date:  2023/06/30 04:52  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  Disclosure of this information could compromise the protection of commercial interests, including the intellectual property of both us and our customers. | General Comments:  We supports the statement made by FCJ on the issues of proposed restriction,as per attached in Section IV. |
| Answer to specific info request 1:  Comments are attached in Section V. |
| Answer to specific info request 2:  Comments are attached in Section V. |
| Answer to specific info request 5:  Comments are attached in Section V. |
| Answer to specific info request 7:  Comments are attached in Section V. |

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| 5983 | Date:  2023/06/30 06:57  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan  Attachment:  <redacted>  Privacy statement:  Test data Product drawing | General Comments:  - |
| Answer to specific info request 1:  Other niche applications |
| Answer to specific info request 6:  a. Types of PFAS PTFE, FKMs, Bisphenol AF b. Major functions of PFAS It is installed in the hydraulically operated cylinder part of construction, industrial, agricultural and robot machines to prevent leakage of hydraulic fluid and to suppress abnormal vibration to prevent damage to the cylinder. They provide function and safety until the product life of the equipment (about 20 years) without deterioration by lubricating oil. g. Substitution is not technically or economically feasible Multiple seals and wear bands are installed inside hydraulic cylinders of construction, industrial, agricultural and robot machines. These convert the pressure of the hydraulic fluid to reciprocating motion, thus preventing leakage of the hydraulic fluid and enduring sliding heat up to 150 deg C. NBR, ACM and VMQ other than FKM can ensure function and safety until the product life (20 years) when the normal temperature is around 100 deg C. However, the sliding speed increases due to the demand for high performance equipment, and the temperature of these products reaches 150 deg C. As the attached data shows, except for FKM, the product life is reduced to 1/10 at 150 degrees Celsius compared to 100 degrees Celsius. That is, the parts need to be replaced once every 2 years. Thus, the number of 0 replacements increases to more than 10 over the life of the product, and the amount of waste with environmental impact increases by more than 10 times. The replacement of seals and wear bands requires the disassembly of cylinders, which is a significant financial burden. If not replaced, in the worst case, an accident due to broken cylinders or a fire associated with an oil leak could result in a loss of life. Thus, FKM (perfluoro and polyfluoropolymers) is an important material to reduce the environmental impact and protect human life. PTFE (including filled PTFE), which has similar performance to FKM, can also be used for seals and wear bands. PTFE simultaneously has oil resistance, heat resistance, and wear resistance that do not deteriorate due to hydraulic fluid, sliding heat generation, and friction, as well as low sliding resistance, in particular, which can suppress stick-slip occurrence. The use of PTFE is a very beneficial option because stick-slip induces abnormal vibration and causes sudden cylinder failure. Therefore, FKM (perfluoro and polyfluoropolymers) and PTFE (including filled PTFE) are not subject to regulation, and its continued use with Time-unlimited is essential. Also, banning supply parts from coming to market after a certain deadline violates CE principles and Green Deal goals because it prevents the repair and inspection of vehicles already on the market. Type certification systems and supplies should be recognized as important requirements for exemptions. In addition, the use of FKM (perfluoro and polyfluoropolymers) to form molded products with rubber elasticity requires the use of bisphenol AF, a type of PFAS, as a cross-linking agent. Proposed regulations for bisphenol AF have been published in the "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment". It can be said that the proposed regulations have established upper limits for the release of bisphenol AF into the environment and that the environmental impact has been sufficiently examined. The threshold for bisphenol AF in molded products should be in accordance with the values in this proposed legislation. The use of FKM (perfluoro and polyfluoropolymers) is not subject to PFAS regulations and its continued use with Time-unlimited is essential. |

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| 5984 | Date:  2023/06/30 07:09  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan | General Comments:  - |
| Answer to specific info request 1:  Transport |
| Answer to specific info request 7:  Wear bands used for shock absorbers in suspension of transport vehicles Produced by NOK and supplied to the EU. a. Types of PFAS PTFE b. Major functions of PFAS They are used in the shock absorbers of the suspensions in the chassis of the vehicle, which dampen the vibration of the vehicle body to stabilize the attitude and maneuverability of the vehicle body, thereby contributing to the prevention of vehicle accidents. They provide function and safety until the product life of the vehicle (approximately 20 years) without deterioration due to hydraulic fluid, sliding heat generation and friction wear. g. Substitution is not technically or economically feasible A vehicle chassis requires a suspension to dampen body vibration and stabilize body posture and steering, and shock absorbers are used for suspension components. The shock absorbers consist of a cylinder and a piston, and the piston is equipped with a wear band to stabilize reciprocating motion. Since the wear band reciprocates violently in oil, only PTFE (including PTFE with filler), which simultaneously provides oil resistance, heat resistance, and wear resistance without deterioration due to hydraulic fluid, sliding heat generation, and friction, is applicable. When resins other than PTFE, which do not simultaneously have these characteristics, are used, parts will be repaired and replaced more frequently than when PTFE is used. In other words, the economic burden of repair will increase, and the amount of waste that becomes an environmentally harmful substance will increase as a result of replacement. If not replaced, the running stability of the car body will be impaired, and there is a concern about the impact of traffic accidents on human lives. In addition, PTFE has low sliding resistance and can suppress the occurrence of stick slip. The use of PTFE is very beneficial in preventing accidents and protecting human lives because stick slip induces abnormal vibration and causes sudden suspension failure. Therefore, it is essential that PTFE (including PTFE with filler) be exempted from the regulations and continued use with Time-unlimited. The above is exactly the same for suspensions of construction, industrial and agricultural machines. It is against the idea of the ELV Directive to prohibit the launch of vehicles after a certain deadline after type approval because it prevents recovery of development costs of vehicles. Banning the launch of supply parts after a certain deadline violates CE principles and Green Deal goals because it prevents the repair and inspection of vehicles already on the market. Supplies should be recognized as an important requirement for exemption. |

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| 5985 | Date:  2023/06/30 07:15  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  NOK CORPORATION  Org. country:  Japan | General Comments:  - |
| Answer to specific info request 1:  Transport |
| Answer to specific info request 7:  Thrust washers and seal rings mounted on shafts inside transports' transmissions Produced by NOK and supplied to the EU. a. Types of PFAS PTFE b. Major functions of PFAS Located inside the vehicle's transmission, the thrust washer prevents seizure of the shaft end face of the rotating shaft, and the seal ring prevents leakage of lubricating oil on the rotating and reciprocating shafts. It provides functionality and safety until the product life of the vehicle (approximately 20 years) without deterioration due to hydraulic fluid, sliding heat generation or friction wear. g. Substitution is not technically or economically feasible There are many types of transmission in vehicles, consisting of multiple rotary and reciprocating shafts. Thrust washers receive an axial load at the axial end face of the rotary shaft to prevent metal from baking into each other. Seal rings are mounted on the sides of the rotary and reciprocating shafts to prevent leakage of hydraulic fluid. Because thrust washers and seal rings are subjected to high loads and sliding in oil, only PTFE (including filler-filled PTFE), which simultaneously provides oil resistance, heat resistance and wear resistance without deterioration due to hydraulic fluid, sliding heat generation and friction, is applicable. When resins other than PTFE, which do not simultaneously have these characteristics, are used, parts are more frequently repaired and replaced than when PTFE is used. That is, the economic burden of repair increases, and the amount of waste that becomes an environmentally harmful substance increases as a result of replacement. It should be noted that replacement requires removal of the transmission from the engine bay, and the economic burden is as high as approximately EUR 3,000~4,000 per replacement. If it is not replaced, there is a concern that the damage to the transmission may result in an accident or a fire in the vehicle, resulting in loss of life. In addition, PTFE has low sliding resistance and can suppress the occurrence of stick slip. The use of PTFE is very beneficial in preventing accidents and protecting human lives because stick slip induces abnormal vibration and causes sudden transmission failure. Therefore, PTFE (including PTFE with filler) is exempt from the regulation, and its continued use with Time-unlimited is essential. The above is exactly the same for transmissions of construction, industrial and agricultural machines. It is against the idea of the ELV Directive to prohibit the launch of vehicles after a certain deadline after type approval because it prevents recovery of development costs of vehicles. Banning the launch of supply parts after a certain deadline violates CE principles and Green Deal goals because it prevents the repair and inspection of vehicles already on the market. Supplies should be recognized as an important requirement for exemption. |