**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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| 9225 | Date:  2023/09/25 12:38  Type:  BehalfOfAnOrganisation  Org. type:  Academic institution  Org. name:  ETH Zürich  Org. country:  Switzerland  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Production of fluoropolymers |

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| 9226 | Date:  2023/09/25 12:44  Content:  Scope or restriction option analysis  Description of analytical methods  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Trade union  Org. name:  Finnish Textile & Fashion Association  Org. country:  Finland  Attachment: | General Comments:  - |

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| 9227 | Date:  2023/09/25 12:43  Content:  Environmental emissions  Information on alternatives  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  PLASTIKA KRITIS SA  Org. country:  Greece | General Comments:  Fluoropolymer based substances that are now characterized as PFAS, find extensive use in plastic industry as Polymer Processing Aids (PPA). Polymer processing aids are used in plastics to increase the processing efficiency and quality of polymeric compounds while they are particularly useful during the extrusion of polymeric compounds . Their main advantages include reduction or elimination of die built up and melt fracture, lowering die pressure and apparent melt viscosity .Through optimization of the extrusion process , the use of such additives may also allow an increase of the output rate by minimizing many of the consequences of the melt instability that can occur during high shear extrusion. In all cases ,the use of PPA’s allows a wider operating window of process parameters and offers improved quality and cost reduction . At the same time a significant energy saving is also achieved .  There is extensive list of high demanding applications where polymer processing aids are used . The major categories are blown and cast films , pipe and sheet extrusion as well as injection molding applications .  Fluoropolymers have a unique combination of properties, being durable, efficient, reliable, and versatile while their recommended addition rate is very low . The lack of equivalent tecno-economical solutions , makes this kind of substances vital to the plastics industry sector. |
| Answer to specific info request 1:  Polymeric PFASs used as processing aids for production of non-PFAS polymers/plastics |

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| 9228 | Date:  2023/09/25 12:42  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Other contributor  Org. name:  European Society for Paediatric Endocrinology  Org. country:  United Kingdom | General Comments:  The detrimental impact of Per- and polyfluoroalkyl substances on children  ESPE Statement  Existing peer-reviewed studies provide ample evidence for the association between child exposure to endocrine disruptors and the onset of numerous illnesses including endocrine cancer, obesity, disturbed timing of puberty, impaired fertility, neurodevelopment alterations and numerous rare diseases. Exposure is unavoidable and can take place through the placenta, breast milk, toys and plastic bottles as well as the floors babies crawl on.  Per- and polyfluoroalkyl substances (PFAS) are a group of over 10,000 manmade chemicals used as oil and water repellents and coatings for common products including cookware, carpets, and textiles. These Endocrine-Disrupting Chemicals (EDCs) do not breakdown or very slowly over many years when they are released into the environment, and they continue to accumulate over time.1  PFAS are "forever chemicals", chemicals that are very persistent in the environment and in the human body. They are transgenerational and can migrate via the placenta from mother to child during the prenatal period. 2-4 Postnatally PFAS will be taken up via breastmilk5 and later in life via inhalation of dust or by ingestion of PFAS in drinking water, soil, non-stick coating in pans, food packaging products and food, particularly from fish, fruit and eggs.6 New research also indicates that PFAS are dispersed through the air over long distances.7  As is the case for all EDCs in our environment, children are most vulnerable to the exposure to PFAS. This is because of breathing space closer to the floor, lower body weight, differences in water and food intake, developing organ systems and longer lifespans during which toxic effects might manifest.8 Especially infants are extremely vulnerable as the first months of life are known to be a critical window for the programming of later adiposity and endocrine regulation, neurodevelopment and growth. 8-14 Higher serum PFAS levels in infants have also been associated with a lower vaccination response 15,16 Prenatal exposure has for example been associated with the timing of puberty in girls.17 A recent study showed that nearly 60% of children’s textiles labelled “waterproof”, “stain-resistant”, or “environmentally friendly” contained toxic PFAS substances.18  While decision makers including at the EU level have become more aware of the risks that PFAS pose for population health, ESPE has great concerns that current policies and legislation do not accurately address the specific impact PFAS and other endocrine disruptors have on children even before they are born. More should for example be done to avoid early exposure by focusing on the elimination of PFAS in all food, and other products including pans, clothing, toys, food packaging and floors. ESPE considers the recently published PFAS restriction proposal by authorities in The Netherlands, Norway, Germany, Sweden19 an important first step in the right direction.  As outlined in the restriction proposal as well as the EU Chemicals Strategy for Sustainability, PFAS should only be used in ‘essential’ products. Essential for ESPE means that PFAS should only be employed in those uses that are critical for the functioning of society and where no alternatives are available.20  Moreover, In principle only those essential chemicals should be allowed that have a relatively short half-life, meaning that the chemical leaves the human body relatively quickly after exposure. PFOA and PFOS, for example, do not meet this criterion.  Within the next 5 years all PFAS in the EU should be phased out entirely to stop further human exposure and the continuous contamination of our environment.  In addition to better policies, more research is needed to investigate the immediate and long-term effects of PFAS and other EDCs on the development of children from foetus to young adulthood, particularly the impact on the endocrine system. This is essential to better protect and, where possible, mitigate current and future adverse health effects with lifelong impact.  Better tailored policy making and an improved understanding of the risks posed by PFAS in children are crucial to establish a safer environment for our children and society in general.    END   About ESPE The European Society for Paediatric Endocrinology (ESPE) is an international society registered in Europe that promotes the highest levels of clinical care for infants, children and adolescents with endocrine problems throughout the world, including in less advantaged areas. At the EU level it works together with the EU and partner organisations to create a more healthy environment for children and adults.  European Commission Transparency Register: 425992551261-56  REFERENCES  1. Endocrine Society (n.d.), PFAS Chemicals: EDCs Contamination Our Water and Food Supply/ Endocrine Society. PFAS Chemicals: EDCs Contaminating Our Water and Food Supply | Endocrine Society 2. Perez F, Nadal M, Navarro-Ortega A, Fabrega F, Domingo JL, Barcelo D, et al. Accumulation of perfluoroalkyl substances in human tissues. Environ Int. 2013;59:354-62. Accumulation of perfluoroalkyl substances in human tissues - PubMed (nih.gov) 3. Yang L, Li J, Lai J, Luan H, Cai Z, Wang Y, et al. Placental Transfer of Perfluoroalkyl Substances and Associations with Thyroid Hormones: Beijing Prenatal Exposure Study. Sci Rep. 2016;6:21699. Placental Transfer of Perfluoroalkyl Substances and Associations with Thyroid Hormones: Beijing Prenatal Exposure Study | Scientific Reports (nature.com) 4. van Beijsterveldt I, van Zelst BD, van den Berg SAA, de Fluiter KS, van der Steen M, Hokken-Koelega ACS. Longitudinal poly- and perfluoroalkyl substances (PFAS) levels in Dutch infants. Environ Int. 2022;160:107068. Longitudinal poly- and perfluoroalkyl substances (PFAS) levels in Dutch infants - PubMed (nih.gov) 5. van Beijsterveldt I, van Zelst BD, de Fluiter KS, van den Berg SAA, van der Steen M, Hokken-Koelega ACS. Poly- and perfluoroalkyl substances (PFAS) exposure through infant feeding in early life. Environ Int. 2022;164:107274. Poly- and perfluoroalkyl substances (PFAS) exposure through infant feeding in early life - ScienceDirect 6. Chain EPoCitF, Schrenk D, Bignami M, Bodin L, Chipman JK, Del Mazo J, et al. Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA J. 2020;18(9):e06223. Risk to human health related to the presence of perfluoroalkyl substances in food | EFSA (europa.eu) 7. European Environment Agency (2019). Emerging chemical risks in Europe – PFAS. Emerging chemical risks in Europe — ‘PFAS’ — European Environment Agency (europa.eu) 8. Australian Associated Press / American Academy of Pediatrics (2022) Report outlines health effects of PFAS chemicals in children, provides recommendations for testing. Report outlines health effects of PFAS chemicals in children, provides recommendations for testing | AAP News | American Academy of Pediatrics 9. Yang L, Li J, Lai J, Luan H, Cai Z, Wang Y, et al. Placental Transfer of Perfluoroalkyl Substances and Associations with Thyroid Hormones: Beijing Prenatal Exposure Study. Sci Rep. 2016;6:21699. Placental Transfer of Perfluoroalkyl Substances and Associations with Thyroid Hormones: Beijing Prenatal Exposure Study | Scientific Reports (nature.com) 10. Starling AP, Adgate JL, Hamman RF, Kechris K, Calafat AM, Dabelea D. Prenatal exposure to per- and polyfluoroalkyl substances and infant growth and adiposity: the Healthy Start Study. Environ Int. 2019;131:104983. Prenatal exposure to per- and polyfluoroalkyl substances and infant growth and adiposity: the Healthy Start Study - PubMed (nih.gov) 11. Braun JM. Early-life exposure to EDCs: role in childhood obesity and neurodevelopment. Nat Rev Endocrinol. 2017;13(3):161-73. Early-life exposure to EDCs: role in childhood obesity and neurodevelopment - PubMed (nih.gov) 12. Averina M, Brox J, Huber S, Furberg AS. Exposure to perfluoroalkyl substances (PFAS) and dyslipidemia, hypertension and obesity in adolescents. The Fit Futures study. Environ Res. 2021;195:110740. Exposure to perfluoroalkyl substances (PFAS) and dyslipidemia, hypertension and obesity in adolescents. The Fit Futures study - PubMed (nih.gov) 13. Koponen J, Winkens K, Airaksinen R, Berger U, Vestergren R, Cousins IT, et al. Longitudinal trends of per- and polyfluoroalkyl substances in children's serum. Environ Int. 2018;121(Pt 1):591-9. Longitudinal trends of per- and polyfluoroalkyl substances in children's serum - PubMed (nih.gov) 14. Spratlen MJ, Perera FP, Lederman SA, Rauh VA, Robinson M, Kannan K, et al. The association between prenatal exposure to perfluoroalkyl substances and childhood neurodevelopment. Environ Pollut. 2020;263(Pt B):114444. The association between prenatal exposure to perfluoroalkyl substances and childhood neurodevelopment - PubMed (nih.gov) 15. Abraham K, Mielke H, Fromme H, Volkel W, Menzel J, Peiser M, et al. Internal exposure to perfluoroalkyl substances (PFASs) and biological markers in 101 healthy 1-year-old children: associations between levels of perfluorooctanoic acid (PFOA) and vaccine response. Arch Toxicol. 2020;94(6):2131-47. Internal exposure to perfluoroalkyl substances (PFASs) and biological markers in 101 healthy 1-year-old children: associations between levels of perfluorooctanoic acid (PFOA) and vaccine response - PubMed (nih.gov) 16. Grandjean P, Heilmann C, Weihe P, Nielsen F, Mogensen UB, Timmermann A, et al. Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years. J Immunotoxicol. 2017;14(1):188-95. Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years - PubMed (nih.gov) 17. Ernst A, Brix N, Lauridsen LLB, Olsen J, Parner ET, Liew Z, Olsen LH, Ramlau-Hansen CH. Exposure to Perfluoroalkyl Substances during Fetal Life and Pubertal Development in Boys and Girls from the Danish National Birth Cohort. Environ Health Perspect. 2019 Jan;127(1):17004. Exposure to Perfluoroalkyl Substances during Fetal Life and Pubertal Development in Boys and Girls from the Danish National Birth Cohort - PubMed (nih.gov) 18. Rodgers KM, Swartz CH, Occhialini J, Bassignani P, McCurdy M, Schaider LA. How Well Do Product Labels Indicate the Presence of PFAS in Consumer Items Used by Children and Adolescents? Environ. Sci. Technol. 2022, 56, 10, 6294–6304. How Well Do Product Labels Indicate the Presence of PFAS in Consumer Items Used by Children and Adolescents? | Environmental Science & Technology (acs.org) 19. ECHA (2023), ECHA publishes PFAS restriction proposal. All news - ECHA (europa.eu) 20. Juliane Glüge, Rachel London, Ian T. Cousins, Jamie DeWitt, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Sharyle Patton, Xenia Trier, Zhanyun Wang, and Martin Scheringer Environmental Science & Technology 2022 56 (10), 6232-6242 Information Requirements under the Essential-Use Concept: PFAS Case Studies | Environmental Science & Technology (acs.org) |

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| 9229 | Date:  2023/09/25 12:42  Content:  Scope or restriction option analysis  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  GAMBICA  Org. country:  United Kingdom  Attachment: | General Comments:  • Certain compounds with a single isolated -CF2- group are generally understood not to degrade to any of the highly persistent substances that have given rise to the environmental and/or human health i.e., they do not degrade into ‘arrowhead substances’. • Low volume essential industrial applications of PFAS are subject to special handling at end of life and are not disposed of at municipal consumer waste collection sites. • PFAS’s are environmentally persistent and resilient so therefore alternatives are likely to have similar properties. Therefore, a comprehensive analysis is required before alternatives are used to avoid ‘regrettable substitution’. |

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| 9230 | Date:  2023/09/25 12:53  Content:  Scope or restriction option analysis  Hazard or exposure  Baseline  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Comparison between brake hoses with PTFE-core against other ones available on the market. | General Comments:  PFAS are a huge family of synthetic compounds characterized by the presence of an alkyl chain and the bond carbon–fluorine. Due to their unique chemical structure, PFAS have incomparable properties, such as oil and water repellence, high chemical, physical, and temperature resistance, and the ability to act as surfactants. Because of such properties and the structural variability due to the functional groups, PFAS have been widely used in a variety of products and industrial applications. At the current state of the art, the purpose of our participation in ECHA’s public consultation is to support the unfeasible substitution of certain PFAS like fluoropolymers (such as PTFE, FKM, PFPE, and PFA), fundamental for different components intended for automotive uses (brake hoses, rings, coatings, friction materials,...) and manufacturing processes. Furthermore, the “PFAS” term used for the identification of an entire chemical family should specify which are the impacted substances and polymers for suitable regulation and effective controls because more than 10,000 substances fall in the OECD definition of PFAS with different behaviors and they are not detectable by a single analytical method. |
| Answer to specific info request 1:  We highlight the following applications in which PFAS are essential for our sector: - Brake systems for transport, including racing vehicles. - Auxiliaries involved in the manufacturing processes that remain on the finished product. - Auxiliaries for the proper functioning and maintenance of the vehicles. Additionally, in this consultation, we will provide our available data regarding the products themselves, but also we want to stress the point that the manufacturing processes are impacted by the use of PFAS as lubricants, refrigerants, and material of the components of the machinery (such as cables, semiconductors, insulators, rings, seals, valves, and coating). In general, for the design of industrial processes, it is necessary to foresee investment and maintenance costs, as well as the timing for the return on investment, which may take several years. These are factors that contribute to the final economic balance of the Company. For the manufacturing industry is not feasible to redesign and substitute machineries and equipment in a short time. Furthermore, the maintenance of old machinery would halt entire production lines if spare parts are not available and alternative components have not been validated and approved. Our company is configured as end-users of products containing PFAS, therefore we are heavily dependent on a supply chain that at this moment is not able to provide us with any solutions to substitute components, auxiliaries, machinery, and equipment. |
| Answer to specific info request 5:  Our company inquired its supply chain to estimate the tonnage of components containing PFAS involved in our assemblies. Our investigation will continue after the end of the open period of the public consultation. Based on the current collected feedback, we estimate an average volume in the last year of more than 7 million components per 98,000 tons for O-rings, backup rings, brake hoses, gaskets, wear rings, guide rings, boots, diaphragms, brake wear indicators, brake pads, and lubricants. We would like to highlight that this is an initial estimation, based on the responses received and it is not yet complete. As a parallel insight, we evaluated the available data from the International Material Data System (IMDS), a platform dedicated to data exchange on which the automotive sector relies, and we extracted more than 20,000 of our part numbers containing components with PFAS, in particular with fluoropolymers. |
| Answer to specific info request 7:  At the current state of the art, there are no alternative possible substitutes to PFAS. To guarantee essential safety characteristics, the use of PFAS is required. For example, PTFE is part of Brake hoses because it resists higher realistic temperatures instead of other polymers available on the market. Our company inquired about the supply chain to assess new alternatives, but no one of the involved suppliers, that replied, has found yet suitable substitutions in terms of technical specifications and physical-chemical characteristics. Furthermore, the supply chain is not able to provide neither alternatives and innovative solutions nor a timeline for the phase-out. If we consider the best case in which there will be new technologies and alternatives to substitute PFAS in a few of years, the internal evaluation and validation processes within the company, the suppliers, and the customers can take several years before the effective introduction into production. Based on these considerations, we would suggest, at least, maintaining the proposed restriction of a 13,5-year period after EiF in the Annex XV Restriction Report, Restriction Option 2, condition of restriction n°6(o) “applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods” marked for reconsideration because it is still a short time for the automotive sector. Given the uniqueness of PFAS in automotive applications and the controlled supply chain of vehicle end-of-life management, we suggest considering as appropriate to provide an exemption for fluoropolymers in the proposed restriction, as it has been granted to other sectors and applications, or providing an exemption with a timeline to review it as Annex II of ELV Directive when effective and functional alternatives will be consolidated. Furthermore, we suggest also avoiding setting a phase-out timeline for PFAS used in the machinery and equipment and reconsidering the exemptions when there will be available more reliable studies and evidence on fluoropolymers and the R&D will offer new comparable alternatives in terms of performance. |

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| 9231 | Date:  2023/09/25 12:53  Content:  Scope or restriction option analysis  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:  United Kingdom  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Information is to be kept confidential in order to protect our commercial interests on future vehicle and technology strategies, that could be inferred from the information included in the attachment. | General Comments:  Fluoropolymers and fluoroelastomers do not pose any risks in the use phase and end of life phase. The hazards and concerns during the manufacturing phase can be managed with better risk management options that prevent PFAS emissions to the environment. The current derogation timelines do not provide automotive companies sufficient time to safely transition to PFAS free alternatives. The decision to include the refrigerant R1234yf, conflicts with the findings of the United Nations 2022 Assessment Report “Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change”, which concluded that there is no scientific evidence to support the inclusion of R1234yf in the universal PFAS restriction proposal. |
| Answer to specific info request 1:  Information on uses within the automotive sector, particularly uses of fluoropolymers, fluoroelastomers, electronics, batteries and refrigerants are included in the attachment. |
| Answer to specific info request 2:  Information previously provided by ACEA in May, indicates that there is no risk in the use phase and the end of life phase for the use of fluoropolymers and fluoroelastomers in automotive applications. 100% of the risk is in the manufacturing phase, which can be better managed with alternative risk management options. |
| Answer to specific info request 3:  Fluoropolymers and fluoroelastomers can be safely incinerated at end of life, with no harmful PFAS being produced. The main incineration product is HF, which can be removed from the exhaust gas prior to discharge into air. |
| Answer to specific info request 5:  Approximate amounts for our company: 475,000 kg R1234yf used per year. 185,000 kg fluoroelastomers used per year. 107,500 kg fluoropolymers used per year. |
| Answer to specific info request 6:  Please see information provided in the attachment. |
| Answer to specific info request 7:  Please see derogations requested in attachment. |
| Answer to specific info request 8:  Please see information provided in the attachment. |

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| 9232 | Date:  2023/09/25 12:55  Content:  Baseline  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Kern Technik GmbH & Co. KG  Org. country:  Germany | General Comments:  PFAS-Materialien sind integraler Bestandteil von Dichtungs- und Lagermaterialien, die in unseren Produkten für die Hydraulik Anwendung finden und durch deren Einsatz bestimmte notwendige Eigenschaften der Produkte erreicht werden können. 1. Hervorragende chemische Beständigkeit: PFAS-Materialien sind bekannt für ihre außergewöhnliche Beständigkeit gegenüber einer breiten Palette von Chemikalien, einschließlich aggressiver Säuren, Basen und Lösungsmittel. Dies macht sie ideal für Anwendungen, bei denen Dichtungen und Lager mit aggressiven Chemikalien in Kontakt kommen könnten. 2. Temperaturbeständigkeit: PFAS-Materialien behalten ihre physikalischen Eigenschaften bei höheren Temperaturen gut bei, bei mit Temperatur höher belasteten Bauteilen und auch bei großen Temperaturwechseln ein Erfordernis. 3. Langlebigkeit und geringer Verschleiß: PFAS-Materialien zeichnen sich durch ihre hohe Verschleißfestigkeit aus. 4. Niedrige Reibung: PFAS-Materialien weisen eine niedrige Reibung auf, was zu einer geringeren Wärmeentwicklung und einem effizienteren Betrieb von Lagern führt. 5. Geringe Reaktionsneigung: PFAS-Materialien reagieren nicht mit anderen Materialien, was die Möglichkeit von Korrosion oder chemischer Reaktion mit den umgebenden Komponenten verringert. 6. Geringe Leckagerisiken: Aufgrund ihrer ausgezeichneten Dichtungseigenschaften tragen PFAS-Materialien dazu beitragen, Leckagen zu verhindern, besonders wichtig bei hydraulischen Systemen.  Und gerade aufgrund Ihrer Persistenz werden sie eingesetzt, sind aber in Inneren von geschlossenen Systemen und in sehr kleinen Mengen verbaut. Auf der Grundlage des aktuellen Vorschlags zur Beschränkung von PFAS wären alle Hersteller im Maschinen- und Anlagenbau Maschinen- und Anlagenbauindustrie entweder in ihren Produkten oder in ihrer Produktionslinie betroffen. Für beispielsweise Hydraulikkomponenten, Pumpen, Motoren und Ventile sowie Armaturen und Kompressoren sind stark betroffen und werden in der Industrie häufig verwendet. PFAS, meist fluorierte Polymere, werden zum Beispiel häufig in Dichtungen, Schläuchen, Drähten und Beschichtungen verwendet. Während in einigen Fällen "nur" die Leistung der Produkte immens verschlechtern würde, könnten andere Produkte nicht mehr nicht mehr hergestellt, importiert und auf den Markt gebracht werden, so dass die Unternehmen Unternehmen durch ein PFAS-Verbot ganz oder teilweise ihrer Geschäftsgrundlage beraubt würden. Maschinen- und Anlagenbauunternehmen befinden sich oft in der Mitte der Lieferkette. Daher ist die Identifizierung einer betroffenen Partei eine große Herausforderung. Die unzureichende harmonisierte Einstufung von PFAS in der CLP-Verordnung führt dazu, dass keine Informationen Informationen entlang der Lieferkette weitergegeben werden (z. B. über das Sicherheitsdatenblatt), was die Analyse der Betroffenheit und somit Informationen entlang der Lieferketten zu erhalten, welche Stoffe z.B. in Formulierungen oder Zwischenprodukten enthalten sind, zeitaufwändig und in vielen Fällen unmöglich macht. Um Informationen entlang der Lieferketten zu erhalten zu erhalten werden endgültige Listen für besonders besorgniserregende PFAS (mit CAS-Nummern) benötigt. Die Verwendung von PFAS-haltigen Dichtungen und Lagermaterialien in Ventilen und Beschichtungen wird im Beschränkungsvorschlag nur vorübergehend ausgenommen und nur in bestimmten industriellen Anwendungen geführt (z. B. industrielle und gewerbliche Lebens- und Futtermittelproduktion). Diese Bauteile haben jedoch eine sehr hohe Relevanz für die gesamte Industrie (Chemieanlagen, Werkzeug-, Druck-, Papier-, Textil maschinen, etc.). Für industrielle Anwendungen werden hauptsächlich Fluorpolymere verwendet. Einige von ihnen wurden wissenschaftlich als "unbedenkliche Polymere" bewertet (PTFE, ETFE, FEP, PFA, PVDF und VDFco-HFP). Sie sind nachweislich chemisch stabil, ungiftig, nicht biologisch verfügbar, nicht wasserlöslich und nicht mobil. Aus diesen Gründen sind die Fluorpolymere auch zugelassen, zum Beispiel als Materialien für den Lebensmittelkontakt oder in der Medizintechnik zugelassen. Darüber hinaus haben Henry et al. (2018) alle Fluorpolymere als wenig bedenkliche Polymere ein. Eine abweichende Einstufung sollte wissenschaftlich begründet werden. Bei der Bewertung möglicher Alternativen muss im Rahmen einer ganzheitlichen Betrachtung sorgfältig geprüft werden, ob es tatsächlich geeignete; gleichwertige von der Beschränkung betroffenen Nutzungen gibt. Neben den bestehenden technischen Regelungen (z.B. gesetzliche Anforderungen oder Normen) müssen der technologische Reifegrad, sicherheitsrelevante Aspekte; Energieverbrauch, Lebensdauer und andere Faktoren berücksichtigt werden. Bisher wurden nur wenige und meist sehr spezifische zeitlich befristete Ausnahmen für industrielle Anwendungen vorgeschlagen. Viele Verwendungen wurden bisher nicht berücksichtigt. PFAS-haltige Materialien werden in Maschinen und Geräten benötigt, wenn extreme Bedingungen (hohe oder niedrige Temperaturen, hohe Reibungswiderstände, aggressive/korrosive/toxische chemische Bedingungen oder eine Kombination davon ) vorherrschen. Daher werden die meisten bestehenden Industrieanlagen und Anwendungen - auch im Bereich der Zukunftstechnologien (z.B. Brennstoffzelle, Wasserelektrolyse, Wärmepumpe, Solaranlage) - oft keine gleichwertige Alternativen zu den teuren PFAS, die allein schon wegen ihres hohen Preises nicht sorglos verwendet werden. Ein weiteres Problem ist, dass Maschinen und Anlagen für eine jahrzehntelange Lebensdauer gebaut werden. Vor diesem Hintergrund ist es wichtig, dass Ersatz- und Gebrauchtteile im Beschränkungsvorschlag berücksichtigt werden. Es sind weder grundsätzliche Ausnahmen von der Verordnung noch längere Übergangsfristen geplant. Dies bedeutet, dass nach der Übergangsfrist von 18 Monaten Reparaturen oder der regelmäßige Reparaturen oder der regelmäßige Austausch von Verschleißteilen bei langlebigen Produkten, wie zum Beispiel der Austausch von Dichtungen oder Schläuchen in Industrieanlagen, nicht mehr möglich wäre. Selbst wenn es Ausnahmen gibt, werden sie nur für fünf und zwölf Jahre vorgeschlagen. Es ist nicht Es ist nicht klar, ob und wenn ja, wie eine Verlängerung der bestehenden Ausnahmen beantragt werden kann.In Ermangelung standardisierter, einfacher Analysemethoden ist es nicht möglich zu kontrollieren, wie die Umsetzung des Beschränkungsvorschlags durch die Marktaufsicht in Zukunft sichergestellt werden kann, z.B. insbesondere im Hinblick auf importierte PFAS-haltige Produkte. Dies würde dazu führen, dass dass PFAS-haltige Produkte nicht mehr in der EU hergestellt werden, aber möglicherweise weiterhin weiterhin ihren Weg in die EU finden. Ein unkontrollierter Import von PFAS-haltigen Produkten würde zu zu erheblichen Wettbewerbsnachteilen  Wir als Zulieferer für die Maschinen- und Anlagenbauindustrie unterstützt nachdrücklich das Ziel, die als sehr gefährlich eingestuften PFAS, die als sehr gefährlich eingestuft sind (z.B.: CMR, PBT, vPvB, PMT, vPvM oder als ED) in die Umwelt gelangen. In dieser Hinsicht ist die Regulierung dieser als sehr gefährlich eingestuften PFAS gefährlich eingestuften PFAS grundsätzlich richtig, wenn ein Expositionsrisiko besteht. Es ist auch verständlich die PFAS sinnvoll und nach ihrem Risikopotenzial zu gruppieren, um nicht jeden der 10.000 Stoffe einzeln regulieren zu müssen. Aber: 1. Breite der Regelung Der Beschränkungsvorschlag umfasst sowohl F-Gase, niedermolekulare Verbindungen als auch Fluorpolymere und damit mehrere tausend Stoffe. Die Regulierung muss stärker differenzierter sein. Es muss eine umfassende wissenschaftliche Risikobewertung für die eine umfassende wissenschaftliche Risikobewertung durchgeführt werden, und es muss nachgewiesen werden, dass Gruppen von Stoffen die vergleichbare gefährliche Eigenschaften aufweisen. Der risikobasierte Ansatz muss beibehalten werden, damit Verwendungen, von denen kein relevantes Risiko ausgeht, möglich bleiben.  2. Industrielle Anwendungen sind keine Konsumgüter 2.1. Die allgemeine Ausnahmeregelung für Fluorpolymere, die gemäß der OECD-Definition als Polymere von die nach der OECD-Definition als "wenig bedenklich" gelten Fluorpolymere und Stoffe, wie Monomere und Verarbeitungshilfsstoffe, die für die Fluorpolymere und Stoffe wie Monomere und Verarbeitungshilfsstoffe, die für die Herstellung von Fluorpolymeren erforderlich sind, müssen von dem Verbot ausgenommen werden, sofern sichere Verwendung gewährleistet ist. Dies sieht auch die Studie der britischen Health and Safety Executive (HSE) vorsieht. Kurz gesagt, Gruppen mit geringem Risiko (z. B. Fluorelastomere, Fluorpolymere, die als "wenig bedenkliche Polymere" eingestuft werden) oder Verwendungen ohne relevantes Risiko (z. B. Anwendungen in geschlossenen Systemen) müssen ausgenommen werden. 2.2. Ersatzstoffe Bei Anwendungen mit extremen Bedingungen (hohe oder niedrige Temperaturen, hohe Drücke, UV-Strahlung, hoher Reibungswiderstand, aggressive Chemikalien oder eine Kombination davon ), gibt es keine geeigneten Alternativen zu PFAS-haltigen Produkten. Der hohe Preis von Fluorpolymeren schränkt ihre Verwendung ohnehin ein. Diese einzigartigen Materialien werden im Allgemeinen in der Industrie nur im Bedarfsfall eingesetzt. Die Verwendung von PFAS in industriellen Anwendungen (Dichtungen, Schläuchen, Drähten, Ventilen, Kompressoren und Beschichtungen) trägt zur Sicherheit, Ressourceneffizienz und Langlebigkeit von Industrieanlagen, u.a. 2.3. Eintragspfad in die Umwelt Einige PFAS sind mobil und gelangen in die Umwelt. Der Umweltpfad der verschiedenen verschiedenen PFAS-Untergruppen muss berücksichtigt werden. Ausnahmen müssen gelten, wenn es kein relevanter (umweltgefährdender) Eintrag in die Umwelt stattfindet. So stellt beispielsweise eine Fluorpolymerdichtung, die sich im geschlossenen Raum einer Maschine befindet, kein relevantes Risiko dar. 2.4. Ausnahme des industriellen Sektors Es ist notwendig, zwischen Anwendungen im Verbrauchersektor (B2C) und solchen im B2B-Bereich zu unterscheiden. Industrielle Akteure können sicherstellen, dass PFAS, PFAS-haltige Materialien und Produkte über den gesamten Lebenszyklus hinweg professionell gehandhabt werden professionelles Risikomanagement. 3. Längere Übergangsfristen Die im Beschränkungsvorschlag vorgesehene 18-monatige Übergangsfrist ist zu kurz für industriellen Anwendungen zu kurz; ein Zeitraum von mehreren Jahren ist notwendig, um die möglichen Alternativen auf Funktionalität und sichere Anwendung zu testen, sie für den Serieneinsatz zu qualifizieren und in vielen Fällen im Rahmen der EU-Gesetzgebung zuzulassen. Daher müsste die allgemeine Übergangsfrist ebenfalls mehrere Jahre betragen. 4. Unbürokratische Beantragung von neuen Ausnahmen und Verlängerung bestehender Ausnahmen. Um mögliche unüberlegte Anträge zu vermeiden, sollte ein einfaches und unbürokratisches Verfahren für zukünftige Ausnahmen ermöglicht werden. Darüber hinaus muss eine Verlängerung der Ausnahmen sichergestellt werden. 5. - Liste der betroffenen Stoffe Der chemische Geltungsbereich der Beschränkung muss transparent kommuniziert werden durch durch eine Liste der betroffenen Stoffe (einschließlich IUPAC-Namen, CAS-Nummern, EU-Nummern) so dass die Unternehmen die Informationen entlang der internationalen und umfangreichen Lieferkette sammeln können. 6. Ausnahmeregelung für Ersatz- und Gebrauchtteile Für das Inverkehrbringen von Ersatz-, Verschleiß- und Gebrauchtteilen sind Ausnahmen von der Ausnahmen von der Beschränkung sind im Sinne der Nachhaltigkeit und Wirtschaftlichkeit notwendig (Reparatur-als-Produkt-Prinzip). Diese sind unbefristet zu gewähren oder zumindest zumindest für einen deutlich längeren Zeitraum als die derzeit vorgesehenen Übergangsfristen vorsehen. 7. Doppelregulierung vermeiden Es ist unklar, wie sich die universelle Regelung für PFAS mit anderen derzeit diskutierten Regelungen die derzeit diskutiert werden (insbesondere die neue Verordnung über F-Gase, (EU) Nr. 517/2014). Konsistenz und Kohärenz mit anderen EU-Verordnungen müssen gewährleistet sein. |
| Answer to specific info request 1:  Die allgemeine Ausnahmeregelung für Fluorpolymere, die gemäß der OECD-Definition als Polymere von die nach der OECD-Definition als "wenig bedenklich" gelten Fluorpolymere und Stoffe, wie Monomere und Verarbeitungshilfsstoffe, die für die Fluorpolymere und Stoffe wie Monomere und Verarbeitungshilfsstoffe, die für die Herstellung von Fluorpolymeren erforderlich sind, müssen von dem Verbot ausgenommen werden, sofern sichere Verwendung gewährleistet ist. Dies sieht auch die Studie der britischen Health and Safety Executive (HSE) vorsieht. Kurz gesagt, Gruppen mit geringem Risiko (z. B. Fluorelastomere, Fluorpolymere, die als "wenig bedenkliche Polymere" eingestuft werden) oder Verwendungen ohne relevantes Risiko (z. B. Anwendungen in geschlossenen Systemen) müssen ausgenommen werden. |
| Answer to specific info request 5:  Für industrielle Anwendungen werden hauptsächlich Fluorpolymere verwendet. Einige von ihnen wurden wissenschaftlich als "unbedenkliche Polymere" bewertet (PTFE, ETFE, FEP, PFA, PVDF und VDFco-HFP). Sie sind nachweislich chemisch stabil, ungiftig, nicht biologisch verfügbar, nicht wasserlöslich und nicht mobil. |
| Answer to specific info request 6:  PFAS-haltige Materialien werden in Maschinen und Geräten benötigt, wenn extreme Bedingungen (hohe oder niedrige Temperaturen, hohe Reibungswiderstände, aggressive/korrosive/toxische chemische Bedingungen oder eine Kombination davon ) vorherrschen. Daher werden die meisten bestehenden Industrieanlagen und Anwendungen - auch im Bereich der Zukunftstechnologien (z.B. Brennstoffzelle, Wasserelektrolyse, Wärmepumpe, Solaranlage) - oft keine gleichwertige Alternativen zu den teuren PFAS, die allein schon wegen ihres hohen Preises nicht sorglos verwendet werden. Ein weiteres Problem ist, dass Maschinen und Anlagen für eine jahrzehntelange Lebensdauer gebaut werden. Vor diesem Hintergrund ist es wichtig, dass Ersatz- und Gebrauchtteile im Beschränkungsvorschlag berücksichtigt werden. Es sind weder grundsätzliche Ausnahmen von der Verordnung noch längere Übergangsfristen geplant. Dies bedeutet, dass nach der Übergangsfrist von 18 Monaten Reparaturen oder der regelmäßige Reparaturen oder der regelmäßige Austausch von Verschleißteilen bei langlebigen Produkten, wie zum Beispiel der Austausch von Dichtungen oder Schläuchen in Industrieanlagen, nicht mehr möglich wäre. Selbst wenn es Ausnahmen gibt, werden sie nur für fünf und zwölf Jahre vorgeschlagen. Es ist nicht Es ist nicht klar, ob und wenn ja, wie eine Verlängerung der bestehenden Ausnahmen beantragt werden kann.In Ermangelung standardisierter, einfacher Analysemethoden ist es nicht möglich zu kontrollieren, wie die Umsetzung des Beschränkungsvorschlags durch die Marktaufsicht in Zukunft sichergestellt werden kann, z.B. insbesondere im Hinblick auf importierte PFAS-haltige Produkte. Dies würde dazu führen, dass dass PFAS-haltige Produkte nicht mehr in der EU hergestellt werden, aber möglicherweise weiterhin . |
| Answer to specific info request 7:  Die allgemeine Ausnahmeregelung für Fluorpolymere, die gemäß der OECD-Definition als Polymere von die nach der OECD-Definition als "wenig bedenklich" gelten Fluorpolymere und Stoffe, wie Monomere und Verarbeitungshilfsstoffe, die für die Fluorpolymere und Stoffe wie Monomere und Verarbeitungshilfsstoffe, die für die Herstellung von Fluorpolymeren erforderlich sind, müssen von dem Verbot ausgenommen werden, sofern sichere Verwendung gewährleistet ist. Dies sieht auch die Studie der britischen Health and Safety Executive (HSE) vorsieht. Kurz gesagt, Gruppen mit geringem Risiko (z. B. Fluorelastomere, Fluorpolymere, die als "wenig bedenkliche Polymere" eingestuft werden) oder Verwendungen ohne relevantes Risiko (z. B. Anwendungen in geschlossenen Systemen) müssen ausgenommen werden. |
| Answer to specific info request 8:  Bei Anwendungen mit extremen Bedingungen (hohe oder niedrige Temperaturen, hohe Drücke, UV-Strahlung, hoher Reibungswiderstand, aggressive Chemikalien oder eine Kombination davon ), gibt es keine geeigneten Alternativen zu PFAS-haltigen Produkten. Der hohe Preis von Fluorpolymeren schränkt ihre Verwendung ohnehin ein. Diese einzigartigen Materialien werden im Allgemeinen in der Industrie nur im Bedarfsfall eingesetzt. Die Verwendung von PFAS in industriellen Anwendungen (Dichtungen, Schläuchen, Drähten, Ventilen, Kompressoren und Beschichtungen) trägt zur Sicherheit, Ressourceneffizienz und Langlebigkeit von Industrieanlagen). |

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| 9233 | Date:  2023/09/25 12:56  Content:  Scope or restriction option analysis  Hazard or exposure  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  European Plastics Converters (EuPC)  Org. country:  Belgium  Attachment: | General Comments:  Following our initial submission, EuPC intends to comment on specific applications. Since those are very diverse, each application will be covered in a separate submission. This brief addresses the Plastic Energy Storage Systems within the automotive sector. This submission is built upon a survey conducted across plastic energy storage systems providers for the automotive sector in Europe.  In 2021, about 9.7 million new passenger cars were registered in the European Union. [Statista Research Department (2023), New passenger car registrations in the EU up to 2022, https://de.statista.com/statistik/daten/studie/1197724/umfrage/pkw-neuzulassungen-in-der-eu/]. Although the share of electric vehicles is increasing, the vast majority of Europe’s new cars continue to be powered by gasoline or diesel engines [The International Council of Clean Transportation (2022), European Vehicle Market Statistics Pocketbook 2022/23, https://theicct.org/wp-content/uploads/2023/01/ICCT-European-Vehicle-Market-Statistics-Pocketbook\_2022\_23.pdf]. Including plug-in hybrid electric (PHEV), full hybrid electric (HEV), mild hybrid electric (MHEV) vehicles, the projected market share of light vehicles with fuel tanks sold in the EU in 2025 would be 82 % and remain more than one third of new light vehicles sold by 2035. Additionally, the average global “car park” takes roughly two decades to turn over. If half of new cars sold around the world in 2035 are zero-emission vehicles, 70 % of the vehicles on roads will still be burning fuel [Arora, A. et al. (2021), Why Electric Cars Can’t Come Fast Enough, https://web-assets.bcg.com/6c/5f/f6a715ff4b80b917eec574fa5c77/bcg-why-electric-cars-cant-come-fast-enough-apr-2021-r.pdf].  Use of fluoroelastomers in plastic fuel systems: Due to their unique chemical and physical properties, per- and polyfluoroalkyl substances (PFAS) have been widely used in various industrial and commercial applications. Within the automotive sector fluoropolymers are used in several parts of the fuel delivery and energy storage systems, such as seals, gaskets wires and hoses. This includes, without limitations: • Seals, such as o Seals for the fuel delivery module o Quick connects of various fuel and vapor lines o Vapor venting valves o Fill limit vent valves • Fuel hoses connecting the filler pipe and the fuel tank • Seals used for SCR systems • Wire insulation for fuel pumps, gauge/ level senders and grounding of metal components • Typical interface of fuel system and engine or interface of tank and filler pipe to transfer liquid fuel or fuel vapor  In Europe, around 90 % of fuel tank in vehicles are made of plastics (HDPE) [The ITB Group, Ltd. (2022), Automotive fuel systems – 2022 Update, 1-18]. With most plastic fuel storage systems, fluoroelastomers are used because of their remarkable properties regarding heat resistance, stability against aggressive chemicals (different kinds of fuel, ammonia and urea) and low hydrocarbon permeation rates [Drobny, J.G. (2007), Fluoropolymers in automotive applications. Polym. Adv. Technol., 18: 117-121. https://doi.org/10.1002/pat.807]. Due to these properties, fluoroelastomers ensure the leaktightness of the fuel system and limit contamination of fuel to the environment. Moreover, the fluoroelastomer parts used in fuel system limit hydrocarbon evaporative emissions to the atmosphere and are therefore mandatory necessary to meet current and prospective EU regulations on gas emissions for gasoline vehicles (Euro 6 and Euro 7). Besides that, PFAS have shown benefits regarding assembly reason and their self-lubricating properties.  Toxicity: Fluoropolymers are very stable because of their intrinsic physicochemical properties. If lost in the environment, they are therefore currently considered as persistent. However, they do not display any hazardous property/property of concern referred to by the dossier submitter; i.e., bioaccumulation, mobility, long-range transport potential (LRTP), accumulation in plants, ecotoxicity, endocrine activity/endocrine disruption, effects on human health and concerns triggered by a combination of these properties. Moreover, fluoropolymers and fluoroelastomers, such as FKM, PTFE, FEP and ETFE, meet the OECD criteria for polymers of low concern [Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035; Korzeniowski, S. H. et al. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. 2022. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646]. Regarding residual monomers in articles made from fluoropolymers, it is theoretically possible that small quantities of residual monomers can migrate from finished products. Although on PTFE demonstrated that TFE is not detectable in finished articles, manufactured using standard recommended processing conditions, at detection limits down to about 0.01 ppm wt/wt [Society of the Plastics Industry. 2005. SPIs guide to safe handling of fluoropolymers. Washington (DC)].   Fluoropolymers should be excluded from the scope of the restriction: Based on the non-toxic properties described above, fluoropolymers (including fluoroelastomers) should in our view be excluded from the scope of this restriction. We however provide additional information showing both its negligible emission and the disproportionate socio-economic impact that would be linked to its substitution. Some fluoroelastomers may contain residuals such as BPAF but in very low quantities. Please note that BPAF is studied into the restriction on BPA and Bisphenol of similar concern. To avoid double regulation, we therefore request BPAF and its uses in FKM to be exempted from the scope of this restriction and be addressed in the other restriction which is substance specific and more focused.  Needed transition period and inclusion in the proposed derogation combined with a review clause: There are no suitable potential substitutes for fluoroelastomers used in fuel systems meeting the EU regulations on evaporative emissions. Given the long lifetime of vehicles, gasoline powered engines will still be commercialized well beyond the proposed derogation. We would therefore ask for a time unlimited derogation for those or if not possible the longest considered derogation period (Entry into Force + 13.5 years). There is currently considerable uncertainty whether or not suitable alternatives can be Implemented at industrial level within the proposed transition periods. The restriction should therefore include a review clause and process whereby it may be evaluated whether or not the alternatives could be successfully placed on the market potentially allowing if needed extension of those transition periods. We assume that the derogation applying to transport vehicles would apply to fluoropolymers used in fuel systems, but the element relating to “safety” is subjective in its interpretation. However, this definition is too narrow as the use of fluoropolymers and fluoroelastomers is necessary to meet current and future Euro 6/ Euro 7 environmental limits (i.e. necessary for allowing the placing on the market of cars meeting those emissions requirements). Specific clarification would be needed on the applications mentioned above. |
| Answer to specific info request 1:  This comment is related to the following use: Plastic components containing PFAS used in fuel delivery and energy storage systems in the automotive industry. The following fluoropolymers have been reported as used in plastic energy storage systems: • Fluorine Kautschuk Material (FKM) / Fluorinated propylene monomer (FPM) • Fluorosilicone rubber (FVMQ) • Ethylene tetrafluoroethylene (ETFE) • PTFE (EC number: 618-337-2, CAS number: 9002-84-0) • FEP (EC number: 607-524-4, CAS number: 25067-11-2) • THV (1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and 1,1,2,2-tetrafluoroethene, EC number: 607-638-4; CAS number: 25190-89-0) Additionally, following monomers are used for manufacturing the listed polymers: • 1,1-difluoroethylene, VDF (EC number: 200-867-7; CAS number: 75-38-7) • Hexafluoropropene, HFP (EC number: 204-127-4; CAS number: 116-15-4) • Tetrafluoroethylene, TFE (EC number: 204-126-9; CAS number: 116-14-3) |
| Answer to specific info request 2:  A recent study made by Conversio on behalf of pro-K estimates the collected fluoropolymer waste from End-of-life vehicles (ELV) is predominantly incinerated or disposed in landfill (accounting approximately 70 % and 23.3 % of total collected fluoropolymer waste, respectively). For 2020, it was assumed that around 8.6 - 8.7 Mio. ELV were officially collected in the EU27+3 countries [Fluoropolymer Waste in Europe 2020 – End-of-life (EOL) Analysis of Fluoropolymer Applications, Products and Associated Waste Streams." Final Report Made on Behalf of pro-K, Conversio. July 2022., https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf]. From 2011 to 2019, the number of new car registrations in the EU fluctuated between 9.6 13 Mio [European Automobile Manufacturers’ Association (18 May 2023), New passenger car registrations in the EU, https://www.acea.auto/figure/new-passenger-car-registrations-in-eu/]. Therefore, the 8.7 Mio. ELV can be considered as representative for the upcoming decade. The average weight of fluoropolymer and fluoroelastomers components per fuel system can be estimated with 40 g, which accounts for around 350 t fluoropolymer materials collected from ELV fuel systems in the EU27+3 countries in 2020. Fluoropolymers and -elastomers being very stable in the polymeric form, migration is assumed to be negligible. Therefore, only residuals oligomers or monomers are considered to migrate from fluoropolymers and fluoroelastomers. However, the quantities of those molecules being present in the final article are very low (< 50 ppt to < 5 ppm residual monomers and < 1 % wt residual oligomers for FKM, < 1 ppm residual monomers and < 0.1 % concentrations of residual oligomers in PTFE, ETFE and FEP) [Korzeniowski, S. H. et al. (2022) A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646], Henry, B.J. et al. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035]. It can be assumed, that FKM materials accounts for more than half of fluoropolymers/ fluoroelastomers used in fuel systems (around 55.6 %), which amounts around 195 t FKM material in ELV fuel systems per year. To determine the emission of residual monomers from fluoroelastomers in landfill, a migration model has been developed to simulate the release of BPAF from cured FKM in an environmental scenario. For a time period of 20 years and an estimation of 9 kt of FKMS placed on the market in total per year, the modulated emissions to the environment are 9.86 kg. Taking into account the share of 195 t FKM waste collected from ELV fuel systems per year, emissions from residual monomers in fluoropolymers and fluoroelastomers exceeding 1 kg per year are not expected. For more information, please see Initial input into public consultation on the restriction of BPA and Bisphenols of Similar Concern of the Bisphenol AF Consortium and ETRMA from 21 June 2023 (submission #4744). Based on this analysis, the total emissions of PFAS from plastic fuel systems are expected to be in the range of few kg (significantly lower than estimated by the dossier submitter). |
| Answer to specific info request 3:  As stated above, around 70 % of the fluoropolymer waste from ELV is incinerated. Incineration above 850 °C does not release PFAS-related materials nor detectable levels of Trifluoroacetic acid (TFA) [Aleksandrov, K. Waste Incineration of Polytetrafluoroethylene (PTFE) to Evaluate Potential Formation of Per- and Poly-Fluorinated Alkyl Substances (PFAS) in Flue Gas. 2019, 226, 898-906., DOI: https://doi.org/10.1016/j.chemosphere.2019.03.191 ; Taylor, P. H. Investigation of Waste Incineration of Fluorotelomer-Based Polymers as a Potential Source of PFOA in the Environment. Chemosphere 2014, 110, 17-22, DOI: https://doi.org/10.1016/j.chemosphere.2014.02.037; Bakker, J., et al. (2021) Per- and Polyfluorinated Substances in Waste Incinerator Flue Gases. Rijksinstituut voor Volksgezondheid en Milieu (RIVM) Report 2021-0143.DOI: https://doi.org/10.21945/RIVM-2021-0143)]., Gujarat Fluorochemicals Limited (GFL), Karlsruhe Institute of Technology (KIT) & Société Générale de Surveillance (SGS) consulted by the German Federal Environment Agency (UBA), Incineration study on Fluoropolymers at their End-of-Life, https://www.gfl.co.in/upload/pages/64ca54ee691b6f4a8b2649ec9c7b291f.pdf]. Those temperatures can be found in municipal waste incinerators, as they are mandatory according to the Industrial Emissions Directive 2010/75/EU (Article 50), which prescribes that waste incineration plants must be designed to ensure that flue gases reach a temperature of at least 850 °C for at least 2 seconds in order to ensure the proper breakdown of toxic organic substances). |
| Answer to specific info request 5:  5.1 Volumes of fluoroelastomers/ fluoropolymers used in automotive fuel systems According to the information received to our survey, the volume of fuel systems components containing fluoroelastomers/ fluoropolymers is around 700 t/ year. This represents around 16.6 Mio. fuel systems produced and placed on the EU market per year. The EU automobile industry exports more than 6.3 Mio. motor vehicles each year, therefore the number of fuel systems containing fluoroelastomers/ fluoropolymers used in the EU is lower [Eurostat (2023): Found at European Automobile Manufacturers’ Association (22 May 2023), EU exports of motor vehicles, https://www.acea.auto/figure/eu-exports-of-motor-vehicles/]. 5.2. Related emissions during manufacturing of fluoropolymers Concerning the fluoropolymer manufacturing stage, the Fluoropolymers Product Group (FPG) of Plastics Europe established a program focusing on the emission reduction of non-polymeric PFAS chemicals from European fluoropolymer manufacturing, including average emission targets, promoting state-of-the-art technologies to minimize emissions and a commitment to inform downstream users of fluoropolymers on their safe handling of fluoropolymer resins [The Fluoropolymers Product Group (FPG), Plastics Europe (2023), FPG Manufacturing Programme for European Manufacturing sites, https://fluoropolymers.eu/wp-content/uploads/2023/09/FPG-Manufacturing-Programme-for-European-Manufacturing-sites-Final-September-2023.pdf]. 5.3. Related emissions during converting and service life During the masterbatching, compounding and converting stage, the spillage of pellets is negligible, there is only presence of dustiness; although air filters reduce the risk of emitting dust, as well as the presence of filters in water drains prevents the emission into water. As stated in the Annex XV report, polymeric PFASs considered to be stable up to 300 °C [Section B.9.11.3 of Annex B of the Annex XV Restriction report]. During the extrusion of all HDPE material based liquid fluid containers in automotive applications, including gasoline and diesel tanks, as well as SCR tanks or similar, temperatures of max. 250 °C are reached. However, all further manual or automated assembly steps of the fluoroelastomers/ fluoropolymer containing components on final fluid containers are performed at room temperature. During service life in the car, operational temperatures between 40 °C to 80 °C can be reached. Therefore, no significant emissions of polymeric PFAS are expected during manufacturing and service life and the exposure of workers or consumers is assumed to be low. 5.4. Releases during recycling According to the Conversio study, the amount of fluoropolymer waste from ELV being recycled is negligible [Fluoropolymer Waste in Europe 2020 – End-of-life (EOL) Analysis of Fluoropolymer Applications, Products and Associated Waste Streams." Final Report Made on Behalf of pro-K, Conversio. July 2022., https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf]. |
| Answer to specific info request 7:  7.1 Analysis of Alternatives 7.1.1. Properties of fluoroelastomers/ fluoropolymers Fluoroelastomers and fluoropolymers, such as FVMQ, FKM/ FPM, THV, PTFE and FEP, are used as materials in various applications within the automotive fuel system due to their outstanding sealing properties and resistance to fuel. They are showing limited fuel swelling and compatibility with different kind of fuels, including high ethanol content fuel (like E85) and low maintenance requirements during their service life. Moreover, fluoropolymers and fluoroelastomers minimize evaporative hydrocarbon emissions to ensure compliance with the evaporative emission requirements of Euro 6 and Euro 7. 7.1.2. Discussion of technical properties of alternatives compared to fluoroelastomers Based on the information of the survey, the only available alternatives for FVMQ, FKM and THV-based materials are Nitrile Butadiene Rubber (NBR) and Hydrogenated Nitrile Butadiene Rubber (HNBR). Although NBR and HNBR show comparable to slightly weaker properties in regard to their heat resistance and durability, they are lacking in resisting chemicals and corrosion. The key reasons, why NBR and HNBR based materials as an alternative have failed, are: • Could not achieve a finished article suitable for application • Product meeting national or international standards not achieved • Reduction of performance properties (mechanical, insulation, etc.) • Product failure in the final market application It needs to be highlighted, that the Euro 7 proposal determines evaporative emissions limits for petrol fueled M1 and N1 vehicles of 0.50 g at worst day and hot soak [Proposal for a Regulation of the European Parliament and the Council on type-approval of motor vehicles and engines and of systems, components and separate technical units intended for such vehicles, with respect to their emissions and battery durability (Euro 7) and repealing Regulations (EC) No 715/2007 and (EC) No 595/2009, Annex I Table 3]. Currently the Euro 6 regulation lays down evaporative emission limits of 2 g/48 h test period. These legal requirements can only be archived with fluoropolymer-based materials, which makes fluoroelastomers obligatory for gasoline powered fuel systems. Fluoroplastics, such as FEP and ETFE, and fluoroelastomers, such as FKM, show lower permeation rates than NBR and HNBR during tests with different kind of fuels, including fuels containing 10 15 % alcohol [Ferber, E. et al. (2005) "Low Permeation Elastomeric Fuel Hose Requirements and New Fluoroelastomer Materials," SAE Technical Paper 2005-01-2162, https://doi.org/10.4271/2005-01-2162., Stahl, W. and Stevens, R. (1992) "Fuel-Alcohol Permeation Rates of Fluoroelastomers Fluoroplastics, and Other Fuel Resistant Materials," SAE Technical Paper 920163, https://doi.org/10.4271/920163.] Moreover, it was shown that FKM materials are most suitable for diesel and biofuel systems regarding degradation and premature failure [Farfan-Cabrera, L. I. et al. (2018), Deterioration of seals of automotive fuel systems upon exposure to straight Jatropha oil and diesel, Renewable Energy, Volume 127, 125-133, https://doi.org/10.1016/j.renene.2018.04.048]. Furthermore, as mentioned in Annex E of the restriction report, Nitril rubber is lacking in durability (approx. 10 % of the lifetime of fluorocarbon, above 100 °C even lower) [Annex E, page 351, Table E.114]. 7.1.3. Cost of substitution In general, the costs of research and development including qualification and approval of the final product is accounted approx. 500 k€ per fuel system reference. However, for gasoline powered vehicles no alternatives with comparable sealing properties in regard to evaporative emissions is known. Therefore, a substitution with non-fluoropolymer materials is currently not feasible. 7.1.4. Time needed for substitution/potential socio-economic effects For the time being, no alternatives for gasoline powered vehicles are known. 7.2. Socio-economic impact The estimated annual turnover related to fluoroelastomers and fluoropolymers components of the fuel storage systems on EU level accounts more than 1 bn €. In case an exemption from the scope will not be granted, the restriction could impact up to 3000 employees in the affected companies. Moreover, without fluoroelastomers and fluoropolymer-based parts used in the fuel system, gasoline powered vehicles will not be able to meet the EU limits for evaporative emissions. In 2021, around 50 % of the new vehicles sold in EU-27 are gasoline powered engines. Including hybrid vehicles, which can also be powered by gasoline, the share of vehicles being possibly impacted by a restriction of fluoroelastomers is 66 % of the total vehicles sold in 2021 engines [The International Council of Clean Transportation (2022), European Vehicle Market Statistics Pocketbook 2022/23, https://theicct.org/wp-content/uploads/2023/01/ICCT-European-Vehicle-Market-Statistics-Pocketbook\_2022\_23.pdf]. With an estimated share of 69 % by 2025 and 51 % by 2030, the number of gasoline vehicles, HEV, PHEV and MHEV being sold in EU will not significantly decrease within the next 10 years. [Arora, A. et al. (2021), Why Electric Cars Can’t Come Fast Enough, https://web-assets.bcg.com/6c/5f/f6a715ff4b80b917eec574fa5c77/bcg-why-electric-cars-cant-come-fast-enough-apr-2021-r.pdf]. 7.3. Proportionality We have demonstrated above that fluoropolymers and fluoroelastomers do not show toxic properties and are unlikely to lead to the release of hazardous PFAS compounds, whilst the restriction will have an impact on all vehicles powered by gasoline being sold in the EU.   Conclusion/Summary Based on the above, fluoropolymers and fluoroelastomers should in our view be excluded from the scope of this restriction. We provide additional information showing both its negligible emission and the disproportionate socio-economic impact that would be linked to a restriction. For the time being, there are no alternatives with comparable properties available. Taking into account the average lifespan of vehicles being around 12 years, the vast majority of vehicles being used within the next decades will be powered by gasoline. In order to align with EU hydrocarbon emission limits, and to ensure accessibility of spare parts within the transition period of fuel powered vehicles towards electrical vehicles, a minimum transition period of Entry into force +13.5 years has to be provided. |

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| 9234 | Date:  2023/09/25 12:58  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: | General Comments:  Our company supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV. |

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| 9235 | Date:  2023/09/25 12:56  Content:  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  In the regulatory process under PFAS' "REACH restrictions", it was stated that exemptions would be widely sought.  The exemption proposals submitted in the public consultation will be decided after they have been deliberated, but it can be imagined that the deliberations will be like a simplified examination of authorization approval under the REACH Regulation, and can also be understood as an integrated process of authorization and restriction.  This is related to the description in Annex XV, in particular "2.2.2. Discussion of possible regulatory measure".  Therefore, with regard to PFAS restrictions, I would like to propose that an approval process be established so that proposals for exemptions can be accepted and deliberated even after the proposed restrictions have been finalized.  This also alleviates the possibility of unnecessary socio-economic impacts on PFAS restrictions due to the difficulty of ascertaining their use, and provides a forum for dialogue with stakeholders. |

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| 9236 | Date:  2023/09/25 12:59  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Description of analytical methods  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  UCRS - Anima Confindustria  Org. country:  Italy  Attachment:    <redacted> | General Comments:  - |
| Answer to specific info request 1:  - Gas pressure regulators - Safety devices for gas pressure - Complementary equipment for pressure control stations - Complete stations for pressure control and measurement of combustible gases - Fuel gas odorization systems The below listed equipment is an essential resource for safe and reliable use of the gas infrastructure and installations: • Pressure Regulators • Pressure Safety Devices • Filters / separators • Heaters / heater exchangers • Automatic shut-off valves; • Automatic burner control systems; • Gas/air ratio controls; • Multifunctional controls; • Complete Gas pressure control and metering stations for transmission and distribution; • Auxiliary Devices for Gas Pressure Control Stations; • Odorizing systems; • Etc... |
| Answer to specific info request 2:  Gas infrastructure and installations equipment can be disassembled and separated at the end-of-life for processing or re-use in a circularity methodology. The fate of fluoropolymers at the end-of-life in this business sector is controllable and can be any one or more of the following: Recovery and Recycling: Fluoropolymers can be chemically returned back to their building blocks for reconstruction without damage to their properties. Melt-processable fluoropolymers, which excludes PTFE, can be recycled through traditional mechanical methodologies. The challenge for non-melt processable fluoropolymers like PTFE is identifying ways to return materials to a facility that can perform chemical recycling. This is a difficult problem, but not insurmountable. |
| Answer to specific info request 3:  There are available studies that strongly suggest that PTFE, the most stable fluoropolymer, undergoes complete thermal decomposition at a temperature of about 800°C and is safe for incineration at municipal incineration facilities. Therefore, it is assumed that most other fluoropolymers also thermally decompose within similar parameters and are also safe for incineration at most typical municipality incineration facilities. |
| Answer to specific info request 5:   Incorporation of Gas infrastructure and installation equipment as a missing use. Fluoropolymers are clearly differentiated from other substances in this very broad group of PFAS chemicals. There is strong evidence that suggests that these materials will not give rise to situations of concern for human health or the environment, acknowledging as well that industry continues to make significant progress to limit the use of PFAS polymerization aids and to introduce adequate abatement techniques to keep emissions of potentially harmful fluorinated by-products under adequate control. Fluoropolymers are known for providing many beneficial properties simultaneously (combined in single products) that allow the continued development of applications critical to society, not only related to technological progress, but specifically in terms of safety to the population and development of green energy alternatives. |
| Answer to specific info request 6:  The equipment that may be affected by PFAS REACH restriction require high performance and high reliability to prevent failures in products that could result in harm to people and the environment. Availability Non-fluoropolymer alternative materials do not exist today for specific applications due to the harsh operating conditions in which the materials are required to operate. Finding suitable alternatives is extremely challenging and the evaluations require reliable lab and field test, approval, certifications, etc. to verify durability and behavior over time and in any case will be the best secondary and tertiary choices. For example, some industry standards require 5 years of field experience to validate elastomeric materials. Another consequence concerns the spare parts to be provided for maintenance of already in service equipment originally designed including PFAS materials. The non-PFAS spare parts can compromise the original performances and approvals, leading to a possible replacement of the whole equipment. This situation is critical to align with the European core values of sustainability and economic efficiency, as well as the commitment to fostering a culture of repair and reusability. Non-PFAS Elastomers Traditional elastomers such as Ethylene Propylene Diene Monomer (EPDM), Hydrogenated Nitrile Butadiene (H-NBR), and Silicone were considered as alternatives for seals, but were deemed unsuitable due to their inferior chemical resistance, temperature limitations, and mechanical properties. Most elastomers cannot perform at operating conditions that exceed 150°C. Using materials that are not adequate for the operating condition is not recommended and would, at a minimum and best case, require an unrealistic number of maintenance cycles. Furthermore, safety of workers and the environment could be compromised due to increased probability of failure and possible releases of hazardous materials. All potential alternatives, metals, non-PFAS polymers, and non-PFAS elastomers, may lead to increased maintenance cycles and generation of higher amounts of environmental waste. Economic Feasibility Cost is not the deciding factor for use of fluoropolymers in gas infrastructure and applications. Fluoropolymers are typically more expensive than non-PFAS materials. They are used because of their technical requirements. The primary consideration for applications in gas infrastructure and installations is performance to ensure that safe and efficient operations are maintained. Even if alternatives were available today, the time needed for careful and comprehensive engineering work that accompanies a material change in a highly regulated segment can be in excess of years with substitution costs. Substitution costs, while substantial, will pale in comparison to the on-going costs of increased production facility downtime due to more frequent maintenance cycles and shorter life of components caused by decreased performance of any alternative. Another significant consideration is the intensive engineering effort that accompanies a material change in components for Infrastructure. Activities to be conducted include finding and evaluating alternatives, modifying designs, re-qualification testing and re-certification (ATEX, Pressure Equipment Directive 2014/68/EU, GAR), supply chain cadence change, and customer relations. Hazards and Risks Safety is the deciding factor for use of fluoropolymers in gas infrastructure and installations applications. These materials are selected due to their high performance. The use of inferior performing alternatives could lead to a breach of containment and a subsequent release of media, which could harm humans, the environment and critical equipment. Non-Polymeric PFAS Processing Aids in Fluoropolymers Gas infrastructure and installations equipment providers are downstream users of fluoropolymers and do not handle any non-polymeric PFAS. The main concern related to fluoropolymers, in terms of human and environmental exposure, is the use of non-polymeric PFAS as polymerization aids in the manufacturing process, rather than the fluoropolymer itself. The fluoropolymer itself is not toxic, bio-accumulative, and/or water soluble, in contrast to the processing aids. Suppliers are addressing this and making progress on the development of non-fluorinated processing aids to be used in the production of fluoropolymers. It is expected that fluoropolymers will not degrade to other PFAS during normal conditions of use or in the environment. Recent indications received from fluoropolymer suppliers suggest that incineration of fluoropolymer waste at industrial incinerators can achieve complete thermal destruction of fluoropolymers under specific conditions; therefore it could be concluded that the environmental impact of their by-products can be controlled. |
| Answer to specific info request 7:  UCRS is in favor of safeguard of environment and ban of toxic substances emission and fully committed to comply with all relevant environmental laws and regulations in the country. However, due to need of safety, efficiency, and functionality, the use of PFAS is still necessary and derogations should be then assured for in Gas infrastructure and installation applications. In closing, UCRS derogation request is:  Incorporation of Gas infrastructure and installation equipment as a missing use. Fluoropolymers are clearly differentiated from other substances in this very broad group of PFAS chemicals. There is strong evidence that suggests that these materials will not give rise to situations of concern for human health or the environment, acknowledging as well that industry continues to make significant progress to limit the use of PFAS polymerization aids and to introduce adequate abatement techniques to keep emissions of potentially harmful fluorinated by-products under adequate control. Fluoropolymers are known for providing many beneficial properties simultaneously (combined in single products) that allow the continued development of applications critical to society, not only related to technological progress, but specifically in terms of safety to the population and development of green energy alternatives. |
| Answer to specific info request 8:  The Europe oil and gas infrastructure market from oil and gas segment account for USD 3 billion revenue in 2022 (www.gminsights.com). Exclusion of fluoropolymers in gas infrastructure and installations as a use sector and implementation of an all-PFAS ban will have significant socioeconomic implications on the European economy. Furthermore, through the possible elimination of fluoropolymers, the EU could fall behind other countries on technology competitiveness, especially in the area of chemical processing. Potential outcomes include reduction in manufacturing operations resulting in higher imports for everything from food to pharmaceuticals. Material limitations will continue to narrow the scope of technology-related activities that can be accomplished including those critical to Europe’s future, namely alternative energy, transportation, etc.. Materials are critical enablers of these technologies, and a derogation of fluoropolymers will enable Europe to maintain a level playing field, increasing the probability of achieving a successful outcome. All companies who manufacture equipment for gas infrastructure and installations will be affected by the restriction. |