**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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| 5908 | Date:  2023/06/28 09:29  Content:  Hazard or exposure  Baseline  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Austria  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Trade secrete, sensitive customer information, company know how | General Comments:  Attachment to Sector “Chemical Industry” Specific Use case: Gas scrubbers  Frequently chemical processes have by-products like Cl, HCl, HF, SOx or PFAs, that are contained in the exhaust air. In many cases these by-products are extremely aggressive and dangerous to health and to the environment. For the protection of the environment and employees, manufacturers are required by law to reduce/eliminate emissions of such poisonous gases. Thus, special, corrosion resistant gas scrubbers are needed, that are fully resistant to the chemicals.  Depending on the industry and process different kinds of gases are created, which vary in the concentration and temperature. Table 1 will show examples of typical processes and created gases in the chemical industry [1]. The combination of media, concentration and temperature generates a strongly corrosive media. Thus, special corrosion resistant gas scrubbers are needed that are fully resistant to the chemicals.  Pickling of standard steel / HCl Pickling of stainless steel / NOx (NO2/NO), HF Electroplating / Chrome - VI, Nickel, Aerosol Hot-dip galvanise / HCl, Ammonium chloride, solidified zinc vapours Sewage sludge drying / NH3, H2S Battery production / H2SO4, Aerosol Ceramic production / NH3 Chemical industry general / SO2 Foundry / Ammonium Rubber production / Chlorine Fertilizer production / Chlorine Production and processing of Fluoropolymers / HF, PFAs  Experience has shown that steel structures, FRP structures or lined equipment (like rubber linings) are not able to handle most of these very harsh operation conditions.  An optimal solution for solving such heavy corrosion problems in gas scrubbers is the usage of fluorinated melt-extruded thermoplastics. Well-established manufacturing methods for the construction of such scrubbers, like solid construction, bonding to steel, FRP lining (dual-laminate), provide solutions suitable up to high temperatures, see ANNEX I,II and III  We therefore request full exemption of all fluoropolymers like PVDF, ECTFE, FEP and PFA from the restriction proposal. |
| Answer to specific info request 1:  The specific Sector “Gas scrubbers” is not listed in Annex XV. |
| Answer to specific info request 2:  Depending on the chemicals, their temperature and concentration, the corrosion protective lining is selected. Either PVDF, ECTFE, FEP or PFA is used with thickness typically ranging from 2 mm up to 5 mm. Additionally accessories like welding rod, pipes, fittings and stock shapes are need. The larger volume of fluoropolymers used in our company is already produced without the use of fluorinated polymerization aids. To further reduce the risk of emitting small molecular PFAS from the fluoropolymers, most of our suppliers have already announced that they will change their production process to non-fluorinated polymerization aids in the future. Our company plans to use polymers produced with non-fluorinated polymerization aids as soon as they become available. During manufacturing: There is a certain amount of emissions when fluoropolymers are processes at elevated temperature in the thermoplastic state. While the majority of the emissions is expected to be HF, also some small molecular PFAS are expected to emit. In our facility, the main parts of the extrusion line with the highest temperatures (thus the areas where emissions are most likely to occur) are covered with a ventilation hood to suck of fumes/emissions above the extrusion line. The off gases are then cleaned in gas scrubber (which can be lined with fluorpolymers to prevent them from corrosion), before released into the environment. We are committed to implement an emission control strategy to detect PFAS emission and to capture them during processing. We have state of the art technologies in place to avoid loss of fluoropolymer during the production our facility. We capture and recover fluoropolymer waste during manufacturing in processing for recycling. In case recycling is not possible the fluoropolymer-waste is fed into the waste stream in line with current laws and regulations. Incineration is said to effectively destroy PFAS if temperatures are above 850 °C. Storage and handling Proper Packaging avoids PFAS loss during the transportation and storage. After production, products are packed and stored properly. The use-phase: Sheets made from fluoropolymers are used for the lining of gas scrubber equipment (typically columns with diameters from Ø 500 mm up to 2500 mm). It must also be considered that fluoropolymers are installed in the inside area of the tank only. End-of-life: Equipment which is decommissioned after service life (~10-20 years depending on the application) can be collected and deposited or incinerated according to the state of the art and in line with laws and regulations. |
| Answer to specific info request 6:  The production and handling of chemicals can lead to highly aggressive process gases which are extremely corrosive and dangerous to health. For the protection of the environment and employees, manufacturers are required by law to reduce/eliminate emissions of such poisonous gases. Depending on the industry and process different kinds of gases are created, which vary in the concentration and temperature. a) see ANNEX b) Various, reliable, internationally accepted chemical resistance lists/tables (e.g. DVS Codes 2205-1, ISO TR10358; Compass Corrosion Guide), information supplied by the raw material supplier confirm the superior chemical resistance of fluoropolymers against many chemicals. Additional advantages of this material are: - Well approved installation techniques - Good long-term experience with lifetimes of up to 20 years - Due to the very low surface energy of fluoropolymers, a low wettability on the plastic surface can be detected. In terms of chemical processes, a deposition of particles on the liner material is not desired by thinking of cleaning and maintenance - Flame resistance (UL94 classification V0) - Physiological non toxic - Fluoropolymer linings offers simple repair options since the sheet can be welded again after proper preparation in the case of mechanical or thermal damages. c) see ANNEX d) Various, reliable, internationally accepted chemical resistance lists/tables (e.g. DVS Codes 2205-1, ISO TR10358; Compass Corrosion Guide) , information supplied by the raw material supplier confirm the superior chemical resistance of fluoropolymers against many chemicals. While other materials (e.g. PE, PP, PVC, rubber, …) can only handle mild chemicals and lower concentrations, for many applications only the combined properties as exhibited by fluoropolymers enable feasible and economic solutions. Due to the presence of Chlorine and Fluorine in combination with changes in the concentration and pH-Range metals do not show such an universal chemical resistance as pitting corrosion, crevice corrosion has to be expected. At least no cost effective steel materials are available In case of rubber lining systems a limited chemical resistance and operation temperature has to be expected. The amount of filler material, plasticizer and vulcanization has a major influence on the chemical resistance, permeation properties and bonding strength of a lining material. There are several case studies in which a rubber lined equipment was replaced by a fluoropolymer lining system to reach a longer service lifetime of the system. e) Our company is not active in metals, and we do not have the know-how to evaluate possibilities except for polymers. f) no info g) see ANNEX |

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| 5909 | Date:  2023/06/28 09:31  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Dear Ladies and Gentlemen,   We develop, produce and distribute solutions for the industrial automation sector.   Our customer base comes from a wide range of industries with very specific requirements. In order to meet these requirements, PFAS are not easy to replace at the current state of affairs. New developments and substitutes require a lot of time and resources to be integrated into robust products and to replace the currently existing solutions. Short transition periods are unrealistic and would not lead to a sustainable result.   We talk about long lifetimes of our products, we can only guarantee these if we have sufficient knowledge of the replacement material. The characteristic of longevity is one of the most important reasons for our customers to buy a product from us.    With regard to CO2-neutral manufacturing, waste reduction and a healthy economy, PFASs are currently essential for us. Harsh and excessive regulation would harm us, as well as many of our competitors within the EEA, and would not lead to the sustainability we stand for.Dear Ladies and Gentlemen,   We develop, produce and distribute solutions for the industrial automation sector.   Our customer base comes from a wide range of industries with very specific requirements. In order to meet these requirements, PFAS are not easy to replace at the current state of affairs. New developments and substitutes require a lot of time and resources to be integrated into robust products and to replace the currently existing solutions. Short transition periods are unrealistic and would not lead to a sustainable result.   We talk about long lifetimes of our products, we can only guarantee these if we have sufficient knowledge of the replacement material. The characteristic of longevity is one of the most important reasons for our customers to buy a product from us.    With regard to CO2-neutral manufacturing, waste reduction and a healthy economy, PFASs are currently essential for us. Harsh and excessive regulation would harm us, as well as many of our competitors within the EEA, and would not lead to the sustainability we stand for. Another issue for us is the supply of materials, especially electronic components. The market is very tight and a regulation and thus artificial shortage in the EU market will lead to a further escalation of the situation. This would also be an additional competitive advantage for all manufacturing companies outside the EU.   The many issues we have to face as a company slow down every development process and thus our ability to innovate. Our product portfolio comprises about 29,000 products. We manufacture these from about 150,000 different individual components and materials. The mass alone does not allow for an in-depth analysis and for the mass of products we also need the right alternatives.   We also stand for a restriction of PFAS, but not indiscriminately across everything, but where it is sensible, sustainable, ecologically and economically justifiable.  We ask for a longer transition period of at least 10 years and to establish broad and long-term exemptions for certain classes of substances and products, for example for fluoropolymers and for professional and industrial use.  We request to limit the regulation to proven SVHC and thus counteract this arbitrariness. |

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| 5910 | Date:  2023/06/28 09:53  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 det kommer att antas utan att urvattnas. För mig är det mycket viktigt att vi stoppar utsläpp av långlivade kemikalier! Jag är beredd att varor kan få försämrade egenskaper, till exempel att regnjackan inte är lika vattentät eller att mobiltelefonen blir större och tyngre än idag om det gör att PFAS kan sluta användas. |

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| 5911 | Date:  2023/06/28 09:59  Content:  Hazard or exposure  Type:  Individual  Country:  Sweden | General Comments:  Because of its long life it is crucial to understand it needs to be banned if and when it is having a negative effect upon human and all other life. After watching the documentary 'The Devil we know' I beame horrified how exposure to this sort of chemical when freely exposed to it can kill and deform animals and humans. Its not ethical to keep ignore the hazardous effects of letting this substance leak out in our waters and land when it is not a substance that is necessary or safe. Therefore i hope all these sort of group f chemical should be banned for our future generations of babies and becoming mothers and all of our living creatures . This chemical is not necessary for survival why then expose humans to it? No thanks I say Thank you for your time. |

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| 5912 | Date:  2023/06/28 10:03  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:  Det är otroligt viktigt att förbjuda PFAS och att förslaget går igenom i sin helhet då dessa ämnen har en starkt negativ påverkan på miljön och människors hälsa. Både företag och privatpersoner måste vara beredda att ställa om till en mer hållbar produktion och konsumtion, även om det kan innebära att varor och produkter kan upplevas få en försämrad funktion eller bli dyrare. Människors hälsa och en natur utan skadliga miljögifter måste gå före eventuella kommersiella intressen. |

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| 5913 | Date:  2023/06/28 10:19  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:  Finland | General Comments:  I find that the proposal is good as it is, and shall be adopted as such. It is our generation's responsibility to stop the use of persistent chemicals, and I as a consumer do not mind if products lose certain qualities, i.e. if the rain coat is less water repellent. |

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| 5914 | Date:  2023/06/28 10:36  Content:  Information on alternatives  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The file submitted contains company identifiable information. | General Comments:  - |
| Answer to specific info request 1:  Sector: Electronics and semiconductors: Sub-uses: Semiconductors |
| Answer to specific info request 7:  We provide specific information on Photo-imageable materials in the confidential attachment. |

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| 5915 | Date:  2023/06/28 10:57  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:  Begränsningsförslaget i sin nuvarande form bör godkännas utan ändringar enligt min uppfattning. Även om det skulle resultera i varor som inte fullt når upp till nuvarande varor i kvalitet tex regna visande plagg. PSAS får värre konsekvenser än att jag blir lite blöt i störtregn. Deras långlivade egenskaper gör att kommande generationer får betala för vår egoism. Godkänn det nuvarande begränsningsförslaget. |

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| 5916 | Date:  2023/06/28 11:04  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:  Jag tycker begränsningsförslaget är bras om det är och hoppas det ska antas utan att urvattnas. För mig är det mycket viktigt att stoppa långlivade kemikalier i naturen. Jag är beredd att varor kan få sämre egenskaper. Det är ok med mig. Sluta använda PFAS och att det hamnar i naturen. |

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| 5917 | Date:  2023/06/28 11:07  Type:  Individual  Country:  Sweden | General Comments:  - |
| Answer to specific info request 1:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |
| Answer to specific info request 2:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |
| Answer to specific info request 3:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |
| Answer to specific info request 4:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |
| Answer to specific info request 7:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |
| Answer to specific info request 8:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |
| Answer to specific info request 9:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |
| Answer to specific info request 10:  We learned about the negative effects on our university course. Please, let's try to give our children better living conditions without PFAS. |

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| 5918 | Date:  2023/06/28 11:06  Content:  Hazard or exposure  Environmental emissions  Type:  Individual  Country:  Sweden | General Comments:  Vi måste stoppa utsläpp av långlivade kemikalier - då spelar det mindre roll om regnjackan blir mindre vattentät än idag. |

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| 5919 | Date:  2023/06/28 11:09  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 kommer antas utan att urvattnas. För mig är det mycket viktigt att vi stoppar utsläpp av långlivade kemikalier! Jag är beredd att varor kan få försemrade egenskaper, tex att regnjackan inte är lika vattentät eller att mobiltelefonen blir större och tyngre än idag, om det gör att PFAS kan sluta användas. |

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| 5920 | Date:  2023/06/28 11:12  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 kommer antas utan att urvattnas. För mig är det mycket viktigt att vi stoppar utsläpp av långlivade kemikalier! Jag är beredd att varor kan få försemrade egenskaper, tex att regnjackan inte är lika vattentät eller att mobiltelefonen blir större och tyngre än idag, om det gör att PFAS kan sluta användas. |

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| 5921 | Date:  2023/06/28 12:08  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:  I think that the limitation proposal Is good as it is now, and hope it will be adopted without being watered down. For me, it is very important that we stop the release of long-lived chemicals! I am prepared that goods may have deteriorated properties. For example, that the rain jacket is not as waterproof or that the mobile phone is getting bigger and heavier than today, if it means that PFAS can stop being used. |

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| 5922 | Date:  2023/06/28 12:14  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 begränsningförslaget är bra som det är och hoppas att det kommer antas utan att urvattnas. För mig är det mycket viktigt att vi stoppar utsläpp av långlivade kemikalier!! Jag är beredd att varor kan få försämrade egenskaper, tex att regnjackan inte är lika vattentät eller att mobiltelefonen blir större och tyngre än idag, om det gör att PFAS kan sluta användas. |

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| 5923 | Date:  2023/06/28 14:24  Content:  Scope or restriction option analysis  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Festo SE & Co. KG  Org. country:  Germany | General Comments:  As a category, mechanical engineering was completely left out. Wherever automation replaces human labour, fluoropolymers are used in specific processes. There is no category for devices or machines that are used to produce vaccines, medicines, medical products, semiconductors, food packaging, food filling, printing products, textiles, PV modules, etc. However, machines are needed that can produce these products and fluoropolymers are often used there. However, machines are needed that can manufacture these products and fluoropolymers are often used in valves, hoses and many other components.  The proposed restriction does not distinguish between fluoropolymers (such as PVDF, ETFE, PCTFE, PFA and PTFE and fluoroelastomers - FPM/FKM, FFPM/FFKM, FVMQ) and other PFAS. Fluoropolymers have unique properties such as exceptionally good temperature and chemical resistance, etc. This combination of properties makes substitution with alternatives in certain applications impossible as of today. In addition, fluoropolymers are different from other PFASs and do not have the problematic environmental and toxicological profiles associated with some PFASs. Furthermore, fluoropolymers are classified by the OECD as "PLC" = Polymer of Low Concern). |
| Answer to specific info request 1:  As a category, mechanical engineering was completely left out. Wherever automation replaces human labour, fluoropolymers are used in specific processes. There is no category for devices or machines that are used to produce vaccines, medicines, medical products, semiconductors, food packaging, food filling, printing products, textiles, PV modules, etc. However, machines are needed that can produce these products and fluoropolymers are often used there. However, machines are needed that can manufacture these products and fluoropolymers are often used in valves, hoses and many other components. |
| Answer to specific info request 2:  Our products are components for automation and mechanical engineering and are used in many industries. A large proportion of the fluoroplastics and fluoroelastomers used in our products are lost in the end-of-life phase as built-in components in the recycling of metals, because they are melted down together with the metal scrap, or they are incinerated in waste incineration plants as industrial waste at very high temperatures of more than 800°C. As components for mechanical engineering, our products are mainly made of metals (aluminium, steel, copper), and the seals and housings used are melted down as a small proportion during recycling. In both the recycling processes for metals and the thermal utilisation of plastics in waste incineration plants, this is done at temperatures above 800°C. This ensures that the materials contained in the product are not lost. This ensures that the PFASs present in the product are destroyed. With proper incineration or recycling, no PFASs are released into the environment. Appropriate control systems must be installed to ensure that these processes function properly. Mechanical engineering is also obliged to audit these processes again and again. With the shortage of fluorspar as a raw material looming in the medium term, it is absolutely necessary to implement recycling cycles in the next few years in order to keep the fluoropolymers in the cycle. In closed processes, this can and must function without emissions. |
| Answer to specific info request 5:  The total tonnage of fluoroplastics, fluoroelastomers and PFPE greases processed by us in 2020 is about 80t. The quantity was included in the categories "Construction products", "Food contact materials and packaging" and "Electronics and semiconductors". However, this quantity went into machines for the production of these products. |
| Answer to specific info request 6:  The green category of Table A.1. also lacks applications, e.g. processing and filling of food, equipment for the manufacture of medical products, equipment for the manufacture of electronics, etc. The category "mechanical engineering and components for mechanical engineering" is not to be found in the Annex XV Report. However, this sector is enormously important for the production of many products that are essential for our society. For the production of medicines, foodstuffs, textiles, fuels, etc., valves, drives, hoses and many other components are needed in machines in which fluoropolymers must be used as seals, greases, etc., because the production conditions make materials with the unique property profile of fluoropolymers necessary. Machines go into all industries and components for machines can be used in all the applications mentioned. |
| Answer to specific info request 7:  Fluoroplastics, fluoroelastomers are already used today only if there are no equivalent alternatives due to their high price 75% of our product range is affected by a PFAS restriction. We would no longer be able to manufacture 35% of our products and thus no longer be able to serve the essential applications in mechanical engineering already mentioned. Alternative materials are conceivable for 40% of our products, but would severely restrict the range of application and performance of our products and then also of the machine. However, the qualification of these alternatives would take a very long time of at least 5 years and would be associated with corresponding additional costs. |
| Answer to specific info request 10:  There is a dynamic development in this field, but for many of the 10,000 PFAS there is still no clear detection method. In addition, experience has shown that the testing capacities of the testing laboratories are very limited. The proposal to involve testing laboratories for the detection of PFAS is currently unrealistic, considering the number of laboratories that can perform the detection and the number of products to be tested. We are convinced that such an obligation cannot be implemented when the regulation comes into force and would have to be provided with a generous transition period. |

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| 5924 | Date:  2023/06/28 14:40  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:  For me it is Bert important to forbid harmful chemicals. I do not mind that some products will have lower quality, it is more important that they do not contain PFAS and other toxic chemicals. |

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| 5925 | Date:  2023/06/28 15:03  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 1:  Sektor: Elektronik, Maschinenbau und Automatisierungstechnik Verwendung: ANHANG XV Keine Ausnahme, Einsatz in der Fertigung / Herstellung von Elektronikbauteilen / Geräten zum Vergießen von elektronischen Bauteilen und Sensoren. Für eine längere Lebensdauer und Funktionalität. Einsatzbereich ausschließlich im B2B Bereich. PFAS wird in den verschiedensten Anwendungen in der Elektronik eingesetzt. Anwendungen wie die Hartkunststoffe, Gummi, Dichtungsmittel, Vergussmassen, Harze, Klebebänder und Öle. Außerdem werden viele PFAS-haltige Produkte verwendet, um die hohen Qualitätsanforderungen wie Entflammbarkeit, Dichtigkeit, Isolation, Chemische Beständigkeit, Stoß- und Erschütterungsbeständigkeit zu erfüllen. |
| Answer to specific info request 2:  Die prozentualen Anteile der Emissionen sind wie folgt: - Die Herstellungsphase 0 % - Die Nutzungsphase 0 % - Die End-of-Life-Phase 100 %. Es werden keine PFAS in die Umwelt freigesetzt. PFAS wurden früher zum Teil bei der Polymerisation von Fluorpolymeren verwendet. Mit einer einzigen Ausnahme verwenden die großen Hersteller keine PFAS mehr bei der Herstellung von PTFE-Granulat (Suspension). Auch bei der Herstellung von PTFE-Emulsionsware (Pasten) ist der Ersatz von PFAS bei einem Hersteller in vollem Gange. Andere Hersteller haben ihre Kreisläufe geschlossen, so dass PFAS-kontaminiertes Wasser nicht mehr ungewollt in die Umwelt gelangen kann. |
| Answer to specific info request 3:  Im Verbrennungsprozess gibt es keine Emissionen aus Fluorkunststoffen. Bei der kontrollierten Verbrennung entsteht aus PTFE hauptsächlich Kohlendioxid und Fluorwasserstoff, der durch Filtersysteme in Müllverbrennungsanlagen mit europäischen Standards in ungiftigen Flussspat umgewandelt wird (Quelle: Internet, Artikel zum Verbrennungstest von W.L. Gore & Associates aus 2019 - https://www.ispo. com/maerkte/gore-tex-no-danger-when-burning-ptfe). Es können sich auch Oxide der jeweiligen Füllstoffe bilden. Abfälle von reinem PTFE / TFM aus der Produktion (Späne o.ä.) werden einem Recyclingprozess zugeführt. Daraus werden Rezyklate hergestellt, die nun sehr gute Materialeigenschaften aufweisen. Bei der Verbrennung oder durch andere Umwelteinflüsse (Verwitterung) entstehen keine PFAS. |
| Answer to specific info request 8:  Verwendung: ANHANG XV Keine Ausnahme ANHANG A.3.12. Elektronik und semiconductors\_Table A.48. Verwendung und Eigenschaften von PFAS in der Elektronikindustrie, identifiziert durch stakeholders.\_Coating von elektronischen Bauteilen Funktionen: Hitzebeständigkeit, Feuchtigkeitsbeständigkeit, chemische Beständigkeit Verwendung: < 1 t / Jahr [Nützlichkeit, Vorteile] Fluorierte Klebstoffe haben unvergleichliche Wärme-, Feuchtigkeits-, chemische und elektrische Isolationseigenschaften sowie Stabilität, die in jeder Anwendung eine dauerhafte und dauerhafte Leistung bietet und dazu beiträgt, die Lebensdauer von Produkten wie Automobilen zu verlängern. die in rauen Umgebungen eingesetzt werden. Über alternative Materialien Hitzebeständige Klebstoffe wie Silikon- und Epoxidklebstoffe sind auf dem Markt erhältlich, aber sie haben nicht die gleiche Hitzebeständigkeit, Feuchtigkeitsbeständigkeit, chemische Beständigkeit und elektrische Isolierung wie Fluorklebstoffe. Wir sind der Meinung, dass die vorgeschlagenen PFAS-REACH-Verordnungen dazu führen sollten, dass fluorierte Harze von jeglichen regulatorischen Maßnahmen im Rahmen der REACH-Verordnung ausgenommen werden, wobei ihre Bedeutung für die sichere Verwendung und Anwendung fluorierter Harze anerkannt wird, indem verschiedene PFAS-Gruppen nach ihren jeweiligen Risikobewertungen und Merkmalen unterschieden werden. Insbesondere fordern wir, dass fluorierte Klebstoffe und ihre Rohstoffe, fluorierte Harze, als zeitlich unbegrenzte Verwendungszwecke von den PFAS-Vorschriften ausgenommen werden, da sie ihre Bedeutung anerkennen. |

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| 5926 | Date:  2023/06/28 15:05  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:  The proposed restriction on the manufacture, placing on the market and use of PFAS is an important initiative to safeguard health and wealth of humans and environment. The scientific evidence for the ecotoxicological impact of PFAS is getting solid, and therefore it is important that the proposed restriction is indeed pursued. As a way of mitigating the potential irritation in the general public on a potentially negative impact on e.g. rain coat water persistence could also be included in the proposal. Hence, by informing the public about the risks with PFAS and why a restriction could give a negative impact on a product that is dependent on PFAS for its intended use, a general understanding in the public may be settled. It may also be appreciated that a number of manufacturers have already found alternatives to PFAS in their manufacturing, which may mitigate negative impact on product availability in market areas where PFAS is currently used. |

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| 5927 | Date:  2023/06/28 15:07  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  DIGITALEUROPE  Org. country:  Belgium  Attachment: | General Comments:  On behalf of our members, DIGITALEUROPE requests that the following derogations should be added to the EU PFAS restriction (DIGITALEUROPE is currently gathering technical information to support additional derogation requests): 1) Spare parts for repair of finished consumer electronic equipment already placed on the market, 2) Spare parts for repair of finished professional business-to-business electronic equipment already placed on the market, 3) Re-supply of articles already placed on the market (pre-owned products)  These derogations are critical to help achieve EU goals of avoiding premature obsolescence and for compliance with laws promoting product longevity. The concepts of “right to repair” and allowing resale of pre-owned products have been broadly incorporated into other EU substance restrictions, and other EU REACH restrictions, and it is essential to incorporate them into the EU PFAS restriction to avoid major market disruptions.  Please see in attachment our detailed request. |
| Answer to specific info request 1:  Electronics |

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| 5928 | Date:  2023/06/28 15:11  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  HYDAC Group of Companies  Org. country:  Germany  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Available information is summarized in the appendix. |
| Answer to specific info request 2:  Available information is summarized in the appendix. |
| Answer to specific info request 3:  Available information is summarized in the appendix. |
| Answer to specific info request 5:  Available information is summarized in the appendix. |
| Answer to specific info request 6:  Available information is summarized in the appendix. |
| Answer to specific info request 7:  Available information is summarized in the appendix. |

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| 5929 | Date:  2023/06/28 15:52  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  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Berghof Fluoroplastic Technology GmbH  Org. country:  Germany  Attachment:    <redacted>  Privacy statement:  The confidential attachments include sensible company information (i.e. revenue, supplier information, etc.). Also not open access literature is attached due to possible copyright. It also contains sensitive, confidential customer information. The parties recognize that Confidential Information is unique and valuable and that disclosure or use in violation of this agreement may result in irrepa-rable harm to the discloser for which monetary compensation alone may not provide an adequate remedy. Therefore, the parties agree that in the event of a breach or threatened breach of confidentiality, the discloser shall be entitled to specific performance and injunctive or other equitable relief as a remedy for any breach or threatened breach without the necessity of posting a bond. Any remedy shall be in addition to, and not in lieu of, any equitable relief in the form of damages. | General Comments:  We decided to submit a non-confidential and confidential report (attachments section IV an section V) to elaborate in detail on all the important topics addressed in the ECHA public consultation request. It is recommended to ECHA examiners to evaluate the confidential report, since more detailed and business related data could be provided. Please note that due to time constraints, this document may not include all detailed information about the ‘missing uses – Analysis of alternatives and socio-economic analy-sis’, but further submissions by Berghof Fluoroplastic Technology will provide this information during the course of the public con-sultation. A summary is given below, but note that all detailed information with supporting references and data is presented in the attachments!  Summary:  Scope or restriction option analysis: The scope of our contribution is the processing of fluoropolymers in general, PTFE in particular and more specifically: suspension PTFE. It should be noted that Berghof Fluoroplastic Technology solely processes PTFE manufactured by suspension polymerization (i.e. sPTFE) to obtain sintered PTFE products to serve i) high-density/solid PTFE, ii) porous PTFE, iii) optical PTFE. It is known and confirmed by multiple sPTFE suppliers, that sPTFE does not require PFAS-based processing aids in their manufacturing process. Berghof Fluoroplastic Technology endeavor a supply chain, from raw material to shipped products, without PFAS-of-concern. The consumption of all PTFE types worldwide and in western Europe is 190 and 35 Mio. kg respectively. The suspension PTFE mar-ket size is estimated to reach 1.500 Mio US$ by 2027 after growing at a CAGR of 7,2% from 2022 to 2027. PTFE is a high performance polymer with a unique set of properties, e.g. temperature range from -250 to +260°C, universal chem-ical resistance, hydrophobic properties, excellent dielectric properties, amongst many others. This makes it an extremely valuable materials for the use in many different industries.  Hazard or exposure: PTFE is a polymer of low concern (PLC) in terms of its potential environmental and human health impacts. To this, it is important that suspension PTFE is manufactured without the use of PFAS-of-concern. To confirm this, two other information sources are given related to hazard or exposure, i.e. i) safety data sheets and ii) statements of compliance (e.g. food contact material, USP class VI).  Environmental emissions: During PTFE processing, emissions of PFAS-of-concern due to heating of the PTFE in the sintering process does not occur. Berghof Fluoroplastic Technology has taken measures to further optimize the use of resources to meet the criteria of ‘Operation Clean Sweep’. Berghof Fluoroplastics Technology is an official partner of the 3M’s worldwide unique Fluoropolymer Up-Cycling Project. More than 95% of the generated waste of the production process is reused or recycled! Just a very small portion is too much contaminated (e.g. dirt) and leaves the factory for incineration. It is shown in scientific studies that municipal incineration of fluoropolymers using best available technologies is not a significant source of PFAS and should be considered an acceptable form of waste treatment. The relation between PTFE and its global impact as microplastic (MP) in marine environment was investigat-ed and it was concluded that PTFE plays a medium role when it concerns microplastics. sPTFE at Berghof Fluoroplastic Technology is used for industrial and high tech products only and is not directly applied as consumer goods. Therefore, the contribution of sPT-FE to microplastics is estimated very low. PTFE has a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS.   Baseline: Berghof Fluoroplastic Technology processes PTFE to make a wide variety of PTFE components consisting of high-density/solid PTFE, porous PTFE and optical PTFE for various industries: Semiconductor industry, laboratory equipment/technology, automotive, aerospace, chemical industry, industrial processing, electronics and electrical equipment, photonics (optical industry / light meas-urement), food & beverage, medical technology.  Information on alternatives: PTFE is a high performance material and has many beneficial properties, especially the combination of these properties makes the difference in comparison to alternative materials. High performing polymers permit exceptional end-use-applications, special-ized products at high costs. In general, it can be stated, that PTFE will only be applied, when this is really required for the applica-tion, otherwise a less costly material will be chosen. PTFE is not used for conveniency, but for high-end products where a certain combination of properties is really necessary (essential use!).  Other socio economic analysis (SEA) issues: As soon as the restriction takes effect, it is expected that Berghof Fluoroplastic Technology will lose a very large share of the total revenue which is related to European business. Customer and industry/application demands cannot be met anymore and no com-petitive products can be offered. Relocating the production of Berghof Fluoroplastic Technology to outside Europe is the only al-ternative for the company to remain. This will result in losses of i. jobs, ii. taxes and iii technical/production knowhow in Europe. It will be a challenge (or an impossible mission) to compensate the revenue of the European market outside of Europe. This does not have an impact solely on Berghof Fluoroplastic Technology but on whole Berghof Group as well. The existence of the total Berghof Group is highly endangered because of the entanglement of the PTFE products in the Berghof Group. Other subsidi-aries, i.e. Berghof Products + Instruments and Gigahertz Optik cannot apply these high-quality products with fit-to-purpose proper-ties anymore. The high-value products cannot be offered in the market anymore in a fair and competitive way. Berghof Fluoro-plastic Technology is a significant pilar for the Berghof Company. It can be concluded that the impact of a possible fluoropolymer ban will be devastating to the Berghof Group and its further existence is extremely doubtful.  Request for exemption: Berghof Fluoroplastic Technology cannot comprehend the possible ban of fluoropolymers in general, PTFE in particular and more specifically: suspension PTFE. This fluoropolymer type is a polymer-of-low-concern and can be manufactured without using fluori-nated production aids, like fluorosurfactants. It is already confirmed by various sPTFE manufacturers that PTFE applied at Berghof Fluoroplastic Technology is manufactured with no such production aids. Berghof Fluoroplastic Technology endeavor a supply chain, from raw material to shipped products, without PFAS-of-concern. We are not against a restriction/limitation of hazardous, persistent and mobile PFAS-of-concern, and support a scientific approach differentiating high and low risk substances based on risk assessment. In that way, it should be concluded that fluoropolymers should not be treated in a similar way as other PFAS and should be removed from the ECHA restriction dossier. In general, it can be stated, that PTFE will only be applied, when this is really required for the application, otherwise a less costly material will be chosen. Furthermore, it is no discussion that the fluorine loop should be closed. This is manageable for PTFE ap-plied in industrial applications or in high tech products. These products are traceable and/or recyclable. The application of PTFE in consumer goods should be minimized and only applied if really necessary. The socio-economical impact of a possible restriction or a ban of PTFE on Berghof Fluoroplastic Technology is severe. Relocating the production of Berghof Fluoroplastic Technology to outside Europe is the only alternative for the company to remain. This will result in losses of i. jobs, ii. taxes and iii technical/production knowhow in Europe. The existence of the total Berghof Group in Eu-rope is highly endangered because of the entanglement of the PTFE products in the Berghof subsidiaries. It can be concluded that the impact of a possible fluoropolymer ban will be devastating to the Berghof Group and its further existence is extremely doubt-ful. The uncertainty among various stakeholders, which is already evident in the initial reluctance to invest after the publication of the restriction dossier, already suggests how dramatically and quickly the Berghof Group would be hit by a possible fluoropolymer ban.  General: Fluoropolymers should be exempted from any regulatory action under the REACH restriction!!  Specified: Exemption for PTFE used in high tech products and products and production aids for industrial applications!! |
| Answer to specific info request 1:  Sectors and (sub-)uses: Manufacture / E.2.1 / Sector as a whole Food contact materials and packaging / E.2.3 / Industrial food and feed production Food contact materials and packaging / E.2.3 / Plastic packaging Metal plating and manufacture of metal products / E.2.4 / Manufacture of metal products not addressed elsewhere Applications of fluorinated gases / E.2.8 / Solvents Medical devices / E.2.9 / Diagnostic laboratory testing Medical devices / E.2.9 / Membranes used for venting of medical devices Medical devices / E.2.9 / Packaging of medical devices Transport / E.2.10 / Use of PFASs in applications affecting… Transport / E.2.10 / Mobile Air Conditioning (MAC) Transport / E.2.10 / MAC- and refrigeration in military applications Electronics and semiconductor / E2.11 / Electronics Electronics and semiconductor / E2.11 / Semiconductors Energy sector / 2.12 / Sector as a whole Lubricants / E.2.14 / Sector as a whole Petroleum and mining / E.2.15 / Fluoropolymer applications Missing use: Described in section 2.6 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)) |
| Answer to specific info request 2:  Data are provided in section 1.3 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)). |
| Answer to specific info request 3:  Data are provided in section 1.3 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)). |
| Answer to specific info request 4:  Data are provided in section 1.3 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)). |
| Answer to specific info request 5:  Data are provided in section 1.3 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)). |
| Answer to specific info request 6:  Missing uses: 2.6.1. PTFE for filtration and separation media used in high performance air and liquid applications Industry: Automotive, Electronics and Electrical, Chemical Industry, Semiconductor industry, Food & Beverage Application: Filtration and separation media used in high performance air and liquid applications, i.e. • Pressure compensation elements (e.g. high voltage batteries) • Porous elements with bursting function for passenger safety • Sensor protection caps • high performance membranes that repel water and oil • Parts for crankcase pressure regulation • Diaphragms Data are provided to questions a – g in the attached public consultation reports (non-confidential (Section IV) as well as confiden-tial (Section V)). 2.6.2. PTFE for industrial process equipment Industry: Chemical Industry, Semiconductor industry, Food & Beverage Application: Industrial process equipment, i.e. • Tanks and vessels; i.e. etching tanks, process tanks, storage tanks • Pump components; i.e. pump housings, containment shells, pump impellers, can inserts for pumps, pump dia-phragms/membranes • Bellows • Sealings and gaskets • Bubbling systems • Stirrers • Heaters • Clamps shells • Hollow cylinders • Guiding strips • Filters for liquid processing (see section 2.6.1) Data are provided to questions ‘a – c, g’ in the attached public consultation reports (non-confidential (Section IV) as well as confi-dential (Section V)). Contributions to question d – f to this missing use will be submitted at a later stage. 2.6.3. PTFE for laboratory equipment, laboratory technology Industry: Laboratory equipment / laboratory technology Application: Reactor vessels used in: • Digestion technology • Reactor technology Data are provided to questions ‘a – c, g’ in the attached public consultation reports (non-confidential (Section IV) as well as confi-dential (Section V)). Contributions to question d – f to this missing use will be submitted at a later stage. 2.6.4. PTFE for sensor applications Industry: Electronics and Electrical Application: Sensor applications, i.e. • Microwave level measuring sensor • Pressure measuring sensor • Point level sensor • Capacitive and conductive level sensor • Radiometric level, density and flow sensor Data are provided to questions ‘a – c, g’ in the attached public consultation reports (non-confidential (Section IV) as well as confi-dential (Section V)). Contributions to question d – f to this missing use will be submitted at a later stage. 2.6.5. PTFE for varnishing aids Industry: Painting/varnishing technology (automotive, amongst others) Application: PTFE electrode ring as varnishing aid Data are provided to questions ‘a – c, g’ in the attached public consultation reports (non-confidential (Section IV) as well as confi-dential (Section V)). Contributions to question d – f to this missing use will be submitted at a later stage. 2.6.6. PTFE for transmission and communication Industry: Transmission and communication Application: Wifi antenna parts Data are provided to questions ‘a – c, g’ in the attached public consultation reports (non-confidential (Section IV) as well as confi-dential (Section V)). Contributions to question d – f to this missing use will be submitted at a later stage. 2.6.7. PTFE for optical applications and photonics Industry: Optical industry, light measurement technology Application: Optical properties of PTFE applied in • Reflection standards • Interior of Ulbricht integrating spheres • Diffuse reflectors • Projection screens • Display backdrops • Reflectors for highly intensive radiation sources Data are provided to questions ‘a – c, g’ in the attached public consultation reports (non-confidential (Section IV) as well as confi-dential (Section V)). Contributions to question d – f to this missing use will be submitted at a later stage. |
| Answer to specific info request 9:  PTFE has no degradation potential. This is elaborated in detail in section 1.3 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)). |
| Answer to specific info request 10:  Analytics for PFAS determination if provided in section 1.3 and 1.5 of this report in the attached public consultation re-ports (non-confidential (Section IV) as well as confidential (Section V)). |

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| 5930 | Date:  2023/06/28 16:26  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:  There is an absolute need to forbid usage of all types of PFAS-chemicals that can lead to emissions of these everlasting chemicals in the environment. I heard that a proposal of such regulations is being discussed at the moment. It is important that such regulations will not be full of exemptions, but instead will be strict to all form of chemical usage. I am active in the outdoors industry and also work as a firefighter, two fields of business where PFAS is often used. There are other ways to prevent fire or to keep clothing water repellent than usage of chemicals that harm nature, entire food chains and ultimately ourselves. Thanks for doing a good job keeping these chemicals away from the market! |

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| 5931 | Date:  2023/06/28 16:45  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Transitional period  Type:  Individual  Country:  Sweden | General Comments:  På grund av de hälsorisker som finns och den extremt långa nedbrytningstid som kemikalierna har tycker jag att det är mycket viktigt att de förbjuds, även om det sker gradvis under en övergångsperiod. Jag tycker att förslaget är bra som det ser ut nu och vill inte se att det förändras till det sämre. Vi har redan sett exempel på att det är möjligt att ställa om och med lite tid är jag säker på att det är genomförbart. |

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| 5932 | Date:  2023/06/28 17:03  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  GEMÜ Gebr. Müller Apparatebau GmbH & Co. KG  Org. country:  Germany  Attachment: | General Comments:  Any restriction proposals should differentiate between the various types of PFAS. Bans on the use of all PFAS substances negatively impact the manufacture and use of bioprocessing systems that consumers and patients have come to rely on worldwide. There are no alternatives known which can fullfill the current requiremens and standards in pharmaceutical production. |
| Answer to specific info request 1:  We have identified missing main applications which are not considered in the report: Pharmacy and Biotechnology with the sub-uses: Production of medicines and vaccines. Componentes with fluoropolymers are used in this applications to ensure the quality and purity of the products. |
| Answer to specific info request 3:  Please see attached study about end-of-life emissions of Fluoropolymers, which shows that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment. |
| Answer to specific info request 6:  b) Any restriction proposals should differentiate between the various types of PFAS. Bans on the use of all PFAS substances negatively impact the manufacture and use of bioprocessing systems that consumers and patients have come to rely on worldwide. The unique properties and functions of fluoropolymers, expanded fluoropolymers and fluoropolymer composites provide important benefits to patients and consumers, including improved quality and efficacy and protect against the loss of valuable medicinal products. Fluoropolymers play a critical role in the health & wellness of society. Not all PFASs are the same. Fluoropolymers are a distinct class of PFAS substances that possess a combination of properties that result in unmatched functional performance critical to the products and manufacturing processes they enable, including many biomanufacturing processes. Fluoropolymers have documented low-risk properties; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic. c) all GEMÜ customers |

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| 5933 | Date:  2023/06/28 17:06  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:  I’m seriously concerned about what PFASs, as hormone-disrupting chemicals, may do to the fertility of humans and also animals. They are known to cause several illnesses, such as cancer, ulcerative colitis, and hypothyroidism, beside their impact on fertility. Since PFASs are ‘forever chemicals’ with an exceptionally long environmental half-life, this isn’t a problem that will solve itself. It’s up to legislators and businesses to put an end to their use. |

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| 5934 | Date:  2023/06/28 17:23  Content:  Scope or restriction option analysis  Information on alternatives  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  GEMÜ Gebr. Müller Apparatebau GmbH & Co. KG  Org. country:  Germany  Attachment: | General Comments:  Any restriction proposals should differentiate between the various types of PFAS. Bans on the use of all PFAS substances negatively impact the manufacture and use of food processing systems that consumers have come to rely on worldwide. The unique properties and functions of fluoropolymers, expanded fluoropolymers and fluoropolymer composites provide important benefits, including improved quality and purity. Fluoropolymers play a critical role in the food and beverage supply for our society.  Fluoropolymers are a distinct class of PFAS substances that possess a combination of properties that result in unmatched functional properties. Fluoropolymers have documented low-risk properties; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic. |
| Answer to specific info request 1:  Food contact materials and packaging. Subuse: Industrial food and feed production |
| Answer to specific info request 3:  Please see attached study which shows that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment. |
| Answer to specific info request 5:  We as a company use about 435 tonnes of fluoropolymers in our products each year, mainly for sealings and diaphragms in valves. |

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| 5935 | Date:  2023/06/28 17:28  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Rudolf Gutbrod GmbH  Org. country:  Germany  Attachment:  <redacted> | General Comments:  Rudolf Gutbrod GmbH is a family-owned company that was found in 1964. Currently we employ 120 people in our production in Dettingen/Erms. For 60 years, Gutbrod processes fluoropolymers for all industrial sectors by providing fluoropolymer-coated surfaces. Fluoropolymers are needed in nearly all branches and for most of the industrially produced goods. Our Fluoropolymer-coatings fulfil several needs: - Non-stick application - Corrosion protection - Chemical protection - Insulator Bedsides a lot of different uses, they are especially needed also for the following future industries: - Green hydrogen - Semiconductor industry - Batterie cells - Photovoltaic Rudolf Gutbrod GmbH is a supplier to a lot of customers of those progressive industries:  - Amazon Filters - AMD - Centrotherm International - DAS Environmental - Exateq - Haldor Topsoe - H-TEC - Infineon - Intel - Lapmaster Wolters - Ovivo Waters - Rena - Semsysco - Sicconex - Siltronic - Singulus - SUSS Mictrotec - Thyssen Krupp - Wolfspeed    Further customers are:  - AllessaChemie - Allgaier - BASF Ludwigshafen - BASF PharmaChemikalien - BASF Rudolstadt - BASF Schwarzheide - Bayer CropScience - Bayer HealthCare - Bayer MaterialScience - Bayer Schering - Bayer Technology Services - BMW - Boehringer - Borealis - Cabot - Dow Rheinmünster - DSM - Dynamit Nobel - DyStar - Endress+Hauser - Evonik - Flourchemie Dohna - Hoffmann-LaRoche - Ineos - Jungbunzlauer - KataLeuna - Kemira - Krohne - Lancess - Lenzing AG - LG - Merck - Momentive - OMV - PCK - Puerstinger - Robert Bosch GmbH (Reutlingen und Dresden) - Sachtleben Chemie - Saltigo - Sandoz - Sanofi - Tectrion - Uhde - Umicore - Vinnolit - Wacker Chemie   For all purposes, we do coat with several fluoropolymers, e.g., PFA, ETFE, PTFE, E-CTFE – all of them are falling under the currently by ECHA discussed restrictions. These types of coatings are urgently necessary to fulfill the “Green Deal” that is agreed within the European Union. The result of a restriction of the above mentioned materials means, that industries will be outsourced to non-restricted countries and that the economic impact of Germany/the EU will decrease enormously. This means that million jobs in Germany/EU will be lost, and prosperity therefore will decline. A restriction of fluoropolymers will mean a total economic dependency. Unfortunately, ECHA does not make any difference between different PFAS types and their toxicological profiles. As confirmed by our suppliers, there are no alternatives, that provide similar function to the currently used polymers. Therefore, we urgently request to overthink a total restriction of PFAS in general. |
| Answer to specific info request 1:  - Semiconductors - Electronics - Energy Sector (as a whole) - Medical devices – other coating applications (surgery instruments) - Industrial food and feed production (we coat equipment for production equipment for milk-industry) - Non stick coatings in industrial and professional bakeware - Paper and board packaging |
| Answer to specific info request 2:  During our processes, no harmful substances arise. Our coatings are EU- and FDA-confirm and therefore not harmful. The FDAs of our suppliers (Daikin, AGC, Solvay etc.) are present to ECHA; Gutbrods own coatings are tested and confirmed by Eurofins. |
| Answer to specific info request 3:  Fluorpolymers can be recycled. Company Dyneon in Burgkirchen, Germany, a supplier for different fluoropolymers, owns a plant for upcycling/recycling of fluoropolymers. It’s a chemical procedure, that makes new products out of old ones without loosing quality. Signification Co2 saving are possible due to this procedure, and it is the perfect example for circular economy regarding fluoropolymers. Dyneon started this pilot project in 2015 and it can be expected, that further companies will follow. Also company Covestro aims to have circular economy by doing upcycling and recycling because they are also of the opinion, that the materials themselves are not the problem, as they are highly needed for sustainable mobility, sustainable construction etc. Quelle: https://www.process.vogel.de/pfas-fluorpolymere-ewigkeitschemikalien-dyneon-standort-schliessung-gendorf-green-deal-a-4aa7260d0fcd8627927e142c4ab3dd65/ https://www.3mdeutschland.de/3M/de\_DE/presse-de/pressemeldungen/ganzemeldung/?storyid=f29c372a-a0ce-4ba7-96b3-758490c120d4 https://www.covestro.com/de/sustainability/what-drives-us/circular-economy/joint-solutions?gclid=EAIaIQobChMI-qLSmIf8\_gIVB-Z3Ch25NQ--EAAYASAAEgLg1\_D\_BwE Gutbrods leftovers that arise during our coating/lining procedures are sold to the Asian marked, grinded and processed for cable industry. |
| Answer to specific info request 5:  Rudolf Gutbrod GmbH processes ~ 5 - 6 tons of PFAS per year. |
| Answer to specific info request 8:  According to our suppliers and our own tests, there is no alternative for fluoropolymers on the marked currently. The substitutes that are PFAS-free don’t meet our customers’ needs regarding chemical- and corrosion-protection, non-stick properties, adhesion to the carrier material, lifetime and any other aspects that could somehow be considered. IF our suppliers are able to develop PFAS-free material with similar properties than the current ones, we will take several years to further develop the material ourselves and to implement it on the market. All of our customers need to make tests and field studies in case of any material change. Those studies can take up to 10 years or even longer. |

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| 5936 | Date:  2023/06/28 17:31  Content:  Scope or restriction option analysis  Environmental emissions  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  GEMÜ Gebr. Müller Apparatebau GmbH & Co. KG  Org. country:  Germany  Attachment: | General Comments:  Any restriction proposals should differentiate between the various types of PFAS. Bans on the use of all PFAS substances negatively impact the manufacture and use of cosmetic processing systems that consumers have come to rely on worldwide. The unique properties and functions of fluoropolymers, expanded fluoropolymers and fluoropolymer composites provide important benefits, including improved quality and purity. Fluoropolymers play a critical role in the cosmetic production in our society.  Fluoropolymers are a distinct class of PFAS substances that possess a combination of properties that result in unmatched functional properties. Fluoropolymers have documented low-risk properties; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic. |
| Answer to specific info request 1:  Sector Cosmetics Use: Equioment for the cosmetic production |
| Answer to specific info request 3:  Please see attached study which shows that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment. |
| Answer to specific info request 5:  GEMÜ uses about 430 tonnes of PFAS in our products per year, mainly as sealings and diaphragms in valves. |

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| 5937 | Date:  2023/06/28 18:14  Content:  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  specific uses of PFAS in lubricant is explained. this is to be considered as confidential to ensure protection of intellectual property and commercial interests. | General Comments:  answers are provided in attached document |
| Answer to specific info request 1:  lubricants |
| Answer to specific info request 8:  answers are provided in attached document |

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| 5938 | Date:  2023/06/28 18:34  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:  - |

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| 5939 | Date:  2023/06/28 18:39  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 begränsningsförslaget är bra som det är, och jag vill att det ska antas utan förändringar som gör det mindre värt. Jag anser att det är mycket viktigt att vi stoppar användning av alla långlivade kemikalier. Om vissa produkter får en viss "försämrad" egenskap så är det ett mycket billigt pris, jämfört med de nackdelar som kommer med användandet av t.ex. PFAS |

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| 5940 | Date:  2023/06/28 18:48  Content:  Hazard or exposure  Environmental emissions  Type:  Individual  Country:  Sweden  Privacy statement:  Please stop dangerous chemicals to be used! | General Comments:  - |

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| 5941 | Date:  2023/06/28 19:03  Content:  Scope or restriction option analysis  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment: | General Comments:  A ban on PFAS would be a devastating blow for all industries in Europe as they are needed for all kind of industrial processes and not only in consumer products. Detailed information on these impacts will be given by specific trade bodies such as France Chimie.  For this consultation we specifically wish to bring to the attention of the RAC and SEAC the uses of PFAS in the production of pyrotechnical substances as well as pyrotechnical initiators which are essential solutions without any alternatives for safety and reliability reasons in both civilian and military applications. |
| Answer to specific info request 1:  The applications we will comment on are not identified in Table 9. They impact both the Pyrotechnics sector and the Defense sector. For the following questions we will consider two different impacted key elements of our activity (listed as A & B from here onwards), both of which have implications for both civilian and military uses: A - Pyrotechnic compounds synthesis: PFAS binders are used as additives in the formulation of our RED-OX pyrotechnic compositions where they play a critical role for both the safety of manufacturing and handling of the said compositions. These binders are key to obtain a safe granulometry that will avoid unsafe conditions such as thin deposits on surrounding equipment or clogging in the production process. They will also help guarantee a correct initiation of the pyrotechnical compound and thus safe usage. B - Pyrotechnic high-performance components: both for civilian and military uses, components that are subject to harsh terrain conditions (extreme temperature, resistance to cuts and friction, etc.) and high stress situations (high speed propulsion, shockwaves from other explosions, etc.). These components may be cables sheaths, electronic components, surface treatments, etc. Their resistance to these conditions is key to the safety of the end users as misfires or malfunctions can gravely threaten the workers, the armed forces as well as bystanders. |
| Answer to specific info request 2:  A – Pyrotechnic compounds synthesis: During the manufacture phase the viton used is not transformed. Some of it will be integrated as part of the compound and the rest will be dissolved under solvent. In any case no waste or pollution is released into the water network or in any other way. During the use phase the pyrotechnic compound undergoes a combustion/detonation and no PFAS are released at this stage. The end-of-life phase corresponds with the use phase for most products. For the ones that are not used the only way to safely dispose of them will be to initiate them or burn them. None of the compounds or byproducts will be recycled and the slag will go to specific landfills. The previous statements are backed by information from the book “Metal-Fluorocarbon based Energetic Materials” by Ernst-Christian Koch. B - Pyrotechnic high-performance components: The nature of these components can be extremely varied: specific coatings for cables, casings and shells; manufacturing of electronic components; foams; etc. Most of these elements are delivered to our factory as semi-finished products to be incorporated into our initiators. The producers of these components come from very different industries, and it is therefore not possible to obtain data on and cover such varied cases in detail in this consultation. The impacted sectors will respond to the consultation through their respective trade bodies. |
| Answer to specific info request 3:  The use phase of the pyrotechnic compounds as well as the end-of-life phase both correspond to a combustion / an incineration. No PFAS are released at this stage as the compound undergoes a combustion. The previous statements are backed by information from the book “Metal-Fluorocarbon based Energetic Materials” by Ernst-Christian Koch. |
| Answer to specific info request 4:  For safety and/or secrecy reasons pyrotechnical compounds or components are not recyclable through the regular processes. Therefore, the impact on the recycling industry will remain null. |
| Answer to specific info request 6:  We wish to bring attention to the uses of PFAS in the production of pyrotechnical substances as well as pyrotechnical initiators, such uses relate to the Pyrotechnics and/or Defense sector (Table A.1), both of which are listed as not researched in detail and for which no derogations exist in the proposal. a. Our factory currently uses less than 10 kg of viton per year for all of our pyrotechnic compounds. The PFAS are not altered during the production of the compounds as they are used as a binder. No PFAS are released at the end of life either as it undergoes a combustion. b. PFAS are used as a binder during the production process of highly sensitive pyrotechnical compounds. These binders are key to obtain a safe granulometry that will avoid unsafe conditions such as thin deposits on surrounding equipment or clogging in the production process. They will also help guarantee a correct initiation of the pyrotechnical compound and thus safe usage. c. All companies working in the pyrotechnic industry (both civilian and defense sectors) would be either directly of indirectly impacted. d. e. No studies for alternatives exist as so far these substances were not considered as dangerous, and their reliability and safety advantages are proven. Research for alternatives is a risky process with no guarantees which would be costly and likely require many years. An estimate is not possible at this stage but past experience in research of alternatives for elements of pyrotechnic compounds has proven to be very lengthy and often unsuccessful. f. N/D g. A ban of PFAS on these applications would mean an end to many pyrotechnic programs both in the civilian and defense sectors and may even mean the end of our defense branch and the employment of about 100 people. Furthermore, it would also jeopardize many defense programs and largely impair the ability of our armed forces to operate in safe conditions. In any case the PFAS would be prohibited even for the very specific needs of our industry, there would be major to critical consequences as follows: - At short term, the development of our activities would stop as our company could not anymore manufacture and sell any initiators containing energetic substances made from PFAS materials, being here clarified that PFAS materials are in the formulation of energetic materials that are used in our most demanded initiators. - By short to mid term, the most critical consequence would be the loss of sovereignty and military independence of several nations of the European Community including but not limited to France. - By short to mid term, around 100 people would lose their job at Davey Bickford as our company would not be capable to honor the demand of our customers. - By short to mid term, our company would have to resiliate several important contracts with defense companies, the financial consequences of such terminations is not evaluated at this stage. - By mid to long term, the ending of defense and safety activities at Davey Bickford would also directly impact the principal activity of the company (detonators for the mining industry) due to losses of internal synergy between our different entities, losses of strategic skills and core competences, uncontrolled turnover of staff , etc…More than 500 people might lose their job. |
| Answer to specific info request 8:  No studies for alternatives exist as so far these substances were not considered as dangerous, and their reliability and safety advantages are proven. Research for alternatives is a risky process with no guarantees which would be costly and likely require many years. An estimate is not possible at this stage but past experience in research of alternatives for elements of pyrotechnic compounds has proven to be very lengthy and often unsuccessful. |

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| 5942 | Date:  2023/06/28 19:39  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  European Fire Sprinkler Network  Org. country:  United Kingdom | General Comments:  Fire sprinklers save lives, property and the environment from damage due to fire. The sprinklers themselves are closed with a PTFE seal. This uses 0.03-0.12 g of PTFE per sprinkler, depending on sprinkler type. With 20 million fire sprinklers sold in the EU that represents 0.6 to 2.4 tonnes of PTFE per year. At present the industry does not have an alternative seal material. Even if it did, standards would first need to be update to recognise it and each manufacturer would need to test and recertify each of its sprinkler models. This would take many years. |
| Answer to specific info request 1:  It is not obvious which sector is covered by fire sprinkler systems. We recommend it be separately listed. The sector has annual turnover of €4 billion in the EU and employs tens of thousands of people. |
| Answer to specific info request 2:  At present some fire sprinklers are recovered because of the value of their brass content. It would be possible to recover the PTFE as well if there were somewhere to return it. |
| Answer to specific info request 5:  We estimate the annual tonnage of PTFE used by European fire sprinkler seals at 0.6-2.4 tonnes. At present no alternative material is proven suitable for this application and European standards for fire sprinklers do not extend to the use of other materials for the seals (see EN 12259-14). If another material can be shown to provide a good seal over the decades in which a fire sprinkler is in service, standards would need to be updated to recognise it. At the same time every manufacturer would need to test and recertify each of their fire sprinkler models with this new seal material. Laboratory capacity is limited so this would take many years. |
| Answer to specific info request 6:  Fire sprinkler seals a. 0.6-2.4 tonnes/year of PTFE in fire sprinkler seals. b. PTFE offers a stable seal, resistant to corrosion by water over the decades while a fire sprinkler is in service. c. Eight fire sprinkler manufacturers and 1,000 installers. d. Unknown. No alternative material has been assessed. e. R&D has yet to begin. f. ii. 5-10 years. Each fire sprinkler model from each manufacturer would need to be tested and recertified. Approvals are required by some Member States and in general by insurers, so that each fire sprinkler model would need to be assessed by several laboratories. These laboratories have limited capacity. g. If no substitute could be found, fire sprinkler systems could not be installed. National fire safety regulations require sprinklers in some types of buildings for safety reasons. If these buildings did not comply with fire safety regulations they would not be permitted to open and would therefore not be built. In addition, insurers would be unable to insure some buildings, in particular warehouses, if they were not protected with fire sprinkler systems. Without insurance they could not operate and would therefore not be built. While the sector has EU sales of about €4 billion and employs about 30,000 people the knock-on effects of buildings being refused permission to open or operate would affect a large part of the construction industry and cause major disruption in sectors such as logistics. |

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| 5943 | Date:  2023/06/28 20:36  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:  Förslaget med begränsningar som helhet är utmärkt och behöver inte ändras. Det är oerhört viktigt för våra barn och kommande generationer att dessa kemikalier, som inte bryts ner, hindras från att frigöras i naturen. |

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| 5944 | Date:  2023/06/28 21:13  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:  PFAS är gift, något mänskligheten inte behöver ha. Jag hoppas att begränsningsförslaget kommer att antas utan att det vattnas ur, förslaget är bra som det är. Jag bor i en del i Sverige där vi har mest PFAS I dricksvattnet. Det är det allvarligaste en människa kan utsätta sig för, att dricka pfas. Jag köper gärna produkter och tjänster om de är mer miljövänliga och får mitt köp inte påverkar mänskligheten med mer pfas. |

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| 5945 | Date:  2023/06/28 21:19  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 förslaget är bra som det är. För mig är det mycket viktigt att dessa långlivade ämnen slutar att användas. Jag är beredd på att varor kan få sämre egenskaper t.ex. mindre vattentät regnjacka om det innebär att PFAS kan sluta användas. |

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| 5946 | Date:  2023/06/28 21:42  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:  Finland | General Comments:  Jag önskar att begränsningsförslaget antas som det är, utan att urvattnas. För många produkter finns det redan bra ersättare, t.ex. utekläder, köksprodukter (t.ex. stekpannor, kastruller m.m.) och skidvalla. Största delen av pfas-kemikalierna bryts inte ner i naturen. Jag anser att det är ansvarslöst att släppa ut sådana, då det inte finns metoder och resurser för att sedan avlägsna dem därifrån. Det finns områden var grundvattnet/dricksvattnet förstörts ,och dessa områden kommer med tiden att bli fler. Det är inte ekonomiskt hållbart att rena hela världens dricksvatten från pfas-föreningar, och för djur, fåglar och fiskar är det inte heller möjligt. Det finns inget som tyder på att djur skulle vara mer skyddade från de skadliga effekterna än människor. Det finns forskningsresultat som tyder på att pfas kan orsaka försämrat immunförsvar. Ett globalt försämrat immunförsvar skulle vara en stor katastrof vid nästa pandemi. Det finns annan forskning som tyder på att pfas kan orsaka infertilitet. Förutom att det är en tragedi för den enskilda individen, kan det orsaka stora problem i samhällen där de stora årsgrupperna nu går i pension och åldras. Även för den biologiska mångfalden kan det i framtiden bli en katastrof, ifall pfas-ämnen även påverkar djurens fertilitet. Det finns också misstanke om att de här kemikalierna orsakar cancer och andra allvarliga sjukdomar. Rent dricksvatten, ett friskt liv och en normal fertilitet är så fundamentala behov/rättigheter, att jag inte kan komma på en enda produkt som är värd att riskera dessa saker för. I Finland och Sverige är redan Östersjön/insjöarna så förgiftade att det finns stora begränsningar hur ofta man får äta fisk därifrån. Vi behöver inte mer gifter i naturen, eller fler begränsningar gällande vad som är tryggt att äta. Norden har alltid varit stolt över sin rena natur och rena vatten, den stoltheten känner jag tyvärr inte mera idag. Jag gör ingenting med en telefon, soffa som hålls ren, ett vattenrör som inte läcker, skidvalla eller gore-tex skor, ifall jag har cancer, ifall jag inte har rent vatten att dricka och ren mat att äta. Det finns ingen orsak att släppa ut gifter i naturen som aldrig försvinner och som potentiellt kan vara ett lika stort hot mot mänskligheten som klimatförändringen. Jag önskar att ni fattar ett beslut som jordens barn, fem generationer framåt, kan vara stolta över. Ett pfas förbud kräver stora uppoffringar nu, men det är inget jämfört med de uppoffringar framtida generationer kommer att få göra om vi inte gör något åt saken nu. Jag har slutat använda alla produkter jag vet innehåller pfas, för att mina barn ska ha en bra framtid. Ifall ni, mot alla förhoppningar, väljer att inte införa det planerade förbudet, önskar jag att det åtminstone märks klart och tydligt på alla produkter som innehåller pfas, så att vi som konsumenter kan göra det aktiva valet att lämna bort produkter med dessa ämnen. För tillfället är det svårt att identifiera dessa, t.ex. möbler/textilier innehållande pfas. |

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| 5947 | Date:  2023/06/28 21:47  Content:  Hazard or exposure  Type:  Individual  Country:  Sweden | General Comments:  - |

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| 5948 | Date:  2023/06/28 22:26  Content:  Environmental emissions  Type:  Individual  Country:  Sweden | General Comments:  As an individual I want to express the urgent need of a ban of these toxic substanses which are impossible to get rid of once spread. |

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| 5949 | Date:  2023/06/28 22:29  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 anser att begränsningsförslaget är bra i sin föreslagna form. För mig är det mycket viktigt att långlivade kemikalier stoppas regulatoriskt. |

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| 5950 | Date:  2023/06/28 22:42  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 behövs för att skydda oss och kommande generationer från detta fasansfulla gift. Det är bra som det är och jag hoppas verkligen att det kommer att antas fullt ut. Det är hög tid att vi tar ansvar för både människor, djur, natur och vatten och får ett slut på denna livsfarliga kemikalieväg som vi går mot nu! Jag är fullt medveten om att varor och produkter kan få försämrade egenskaper, t.ex. att joggingskorna inte är lika vattentäta eller att mobiltelefonen blir större och tyngre än idag, om detta resulterar i en PFAS-fri miljö för alla levande organismer på vår jord. TACK på förhand! |

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| 5951 | Date:  2023/06/28 23:05  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:  I want PFAS to be restrained or forbidden. Because they are dangerous for the environment, the animals and for people, for example for the fertility and the risks for cancer. |

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| 5952 | Date:  2023/06/29 00:02  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 begränsningsförslaget är bra som det är och hoppas att det kommer att antas utan att urvattnas. För mig är det mycket viktigt att vi stoppar utsläpp av långlivade kemikalier!! Jag är beredd på att varor kan få försämrade egenskaper till exempel att regnjackor inte är lika vattentäta eller att mobiltelefoner blir större och tyngre än idag om det göra att PFAS kan sluta användas. |

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| 5953 | Date:  2023/06/29 02:06  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:  Långlivade kemikalier förstör vår hälsa, natur och välstånd. Snälla, se till att förslaget antas. Inte urvattnas. PFAS har goda egenskaper men nackdelarna väger mycket tyngre. |

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| 5954 | Date:  2023/06/29 09:08  Type:  Individual  Country:  Sweden | General Comments:  human health is at stake. and the future for our kids. no costs can be higher than that. |

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| 5955 | Date:  2023/06/29 10:02  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 är allvarligt rädd för konsekvenserna av alla farliga kemikalier som släpps ut. Jag ser gärna att individer i västvärlden köper färre nya produkter och räknar med inte fullt lika bekväm tillvaro till följd av en mer välmående natur. Vi klarar vardagen även med en lite lite tyngre mobiltelefon om det betyder att giftiga kemikalier kan förbjudas.  \_\_\_ I'm truly worried of the consequences of all the dangerous chemicals that are pouring out in the nature. I prefer that individuals in Western countries would buy less products and count on bit less comfortable daily life if that would help the nature. We would get along just fine with a heavier cellphone if that is the price for not using toxic chemicals. |

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| 5956 | Date:  2023/06/29 10:59  Content:  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Type:  Individual  Country:  France  Privacy statement:  Pour des raisons de confidentialité, je ne souhaite pas que soit divulguée la raison de l'utilisation de PFAS par ma société | General Comments:  Les Substances perfluoroalkyliques et polyfluoroalkylées apportent une bonne efficacité en termes de non adhésion sur les moules métalliques. Ils remplacent efficacement des traitements de surfaces du type chromage plus onéreux. Le défaut des traitements PFAS sont qu'ils sont moins résistants mécaniquement et doivent être traités plus fréquemment. |
| Answer to specific info request 1:  Utilisation pour ma société : dépôt de téflon sur des moules métalliques pour éviter le collage lors du moulage de pièces en silicones (pions de dureté, plaques ASTM pour la découpe d'éprouvettes) |
| Answer to specific info request 2:  Les moules qui présentent des défauts sont renvoyés à SOFIPLAST pour redépose de téflon |

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| 5957 | Date:  2023/06/29 11:33  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:  PTFE plays an important role in imparting printing suitability to printing inks. If PTFE WAX, which is blended into inks to protect the text and image surfaces of printed materials, is lost, the text and image information cannot be transmitted clearly, If PTFE WAX, which is mixed into inks to protect the text and image surfaces of printed materials, is lost, text and image information cannot be transmitted clearly. This leads to misinformation in daily life, This will lead to an increase in the number of problems in the transmission of misinformation in daily life. In addition, printing speed will be reduced by about 60% in terms of productivity, which will have a negative impact on the social environment. This can be assumed to have a negative impact on the social environment. Furthermore, since PTFE WAX used for printing ink can be utilized for secondary use in essential-use applications by utilizing some recycled materials, we request that the use of PTFE WAX for printing ink applications be permitted as well.  TOKYO PRINTING INK MFG. CO., LTD. supports the statement made by FCJ on the issues of proposed restriction,as per attached in Section IV. |
| Answer to specific info request 1:  Offset printed matter is an essential information transmission medium in our daily lives, and to prevent missing text, images, and other information, PTFE compounds must be added to offset inks at a rate of 1 to 3%. There is no other alternative as an anti-abrasion agent for printed materials. Offset printed materials have printing problems such as adhesion of the front and back of the printed material after printing and rubbing during transportation of the printed material. These printing problems reduce the value of the printed material and may result in defective products. Defective products are disposed of, increasing the environmental impact of re-creation and disposal. The addition of raw materials that increase the coating film strength of the printed surface is essential for controlling printing problems. Therefore, we consider PTFE to be an essential material for the future creation of offset printed materials. |
| Answer to specific info request 5:  PTFE is intentionally added as an anti-abrasion agent for inks and does not cause release to the atmosphere, volatilization, exposure to employees, or runoff into water. |

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| 5958 | Date:  2023/06/29 11:54  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Poland  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:  Mechanical components of high performance rechargeable Lithium-ion batteries |
| Answer to specific info request 2:  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:  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:  Seal gaskets to be used for high-performance rechargeable Lithium-ion batteries applications |

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| 5959 | Date:  2023/06/29 12:24  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 och jag hoppas att det antas i sin nuvarande form. För mig är det viktigt att vi stoppar utsläpp av långlivade kemikalier! Jag är införstådd med och accepterar att vissa varor kan få försämrade egenskaper om PFAS förbjuds. |

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| 5960 | Date:  2023/06/29 12:22  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 kommer antas utan att urvattnas. För mig är det mycket viktigt att vi stoppar utsläpp av långlivade kemikalier. |

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| 5961 | Date:  2023/06/29 12:45  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 att urvattnas! PFAS och långlivade kemikalier måste stoppas eftersom de påverkar miljö för så lång tid framåt och vi kan inte förutse alla konsekvenser. Det finns alternativ och vi måste lägga resurser på att utveckla dessa alternativ istället eller acceptera försämrade produktegenskaper. |

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| 5962 | Date:  2023/06/29 12:57  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  We are concerned that development and (or) supply of medicines in the EU will be severely impacted by the PFAS Restriction as presently drafted, based on a broadened definition of PFAS and the wide applicability across many different uses. The restriction proposal aims at substances and articles without derogating products where marketing is subject to specific regulations. For medicinal products and medical devices, these are granted market authorisations under Directive 2001/83, or permissions under the EU Medical Device Regulation (MDR) or EU In Vitro Device Regulation (IVDR), respectively. Restricting products under marketing authorisation or permission causes regulatory conflicts. The substance group PFAS as defined in the regulation has no common hazardous properties. Fluoropolymers, for example, are non-hazardous, most are considered polymers of low concern by the OECD and some have food contact approval. Persistence of either the substance itself or its degradation products is the property of concern, but PFAS with demonstrated degradability are not derogated as such, so it can not be claimed to be a common property of the regulated group. The long-term goal of reducing emissions can only be achieved by a global restriction of PFAS. Supply of medicines will be severely impacted, as approved active pharmaceutical ingredients (API) and medicines delivered within packaging and (or) with drug delivery devices used to administer the medicinal products under market authorization are in scope of the restriction. The emissions depend on the use of PFAS. In case of fluoropolymers in industrial use, PFAS are still part of the equipment at its end of life, and emissions can be controlled. In case of use of PFAS as chemicals or auxiliaries in manufacture, storage, transport and quality control, substances can be used under controlled conditions to minimise exposure to the lowest level possible. Alternatives do not exist for API. Introduction of fluorine in the API molecule is an essential part of developing efficacious and safe candidates. Any changes to an API molecule would essentially require the development of a completely new candidate. Due to the unique properties of individual molecular structures containing fluorine, alternatives for API, development products and their starting materials and intermediates do not exist, as the function of the substances is on the chemical molecular level. Alternatives for fluoropolymers in production, packaging and devices may exist in some cases. However, the sought after properties are outstanding resistance against heat, light, chemicals, time and abrasion, which is naturally linked to persistence. This means that alternatives are most likely persistent, too. In manufacturing and packaging, the use of fluoropolymers is closely linked to other sustainability considerations (recyclability, long service life or shelf life, production or transport resources/emissions, energy considerations etc.). These environmental trade-offs are not regarded when only the chemical nature of the material is regulated. Benefits of fluoropolymers in production, packaging and devices include thermal and chemical stability, smooth hard surfaces that are easily cleaned and disinfected, and outstanding barrier properties protecting products from air, moisture, impurities, extractables and particles. This safeguards the safety and quality of products throughout their shelf life. The established substitution timelines (5 or 12 years) are tailored to technical substitution. They do not factor in regulatory timelines such as mandatory stability testing or re-submission of market authorisations for regulated products. A ban would restrict patients' access to safe and approved medicine in europe, including cancer and COVID treatment, for which there is no alternative. This results in a shortage of medicinal products. |
| Answer to specific info request 1:  New proposal for a Sector: pharmaceutical and biopharmaceutical industry. This sector is missing from Table 9 of the Annex XV restriction report. Only the use as active ingredient, can coating of pMDI and PCTFE packaging materials are covered in restriction option of the draft restriction. All (sub-) uses are missing for this sector, and are listed in part 6. |
| Answer to specific info request 2:  As emissions depend on the use, this information will be included in the EFPIA final submission. The handling of waste is extensively regulated by law. Producers, owners, transporters, collectors, brokers and traders of waste are subject to extensive waste legislation both in Europe and in Germany. The same applies to waste management, waste recycling, waste disposal and the shipment of waste across national borders. Of course, this legislation also applies to waste containing PFAS. |
| Answer to specific info request 3:  We do not have any data on this, but we would refer you to the New European waste study on fluoroplastics and the EFPIA submission paper. |
| Answer to specific info request 4:  There is a risk that a PFAS ban could be a significant barrier to the circular economy in terms of the usability of recyclates from mechanical recycling. Instead of a general ban on PFAS polymers, it would be much more effective to develop a strategy for the transfer of PFAS polymers into a closed material cycle (circular economy). Their properties make them ideal candidates for the development and establishment of such sustainable and future-proof strategies. |
| Answer to specific info request 5:  As tonnage and emissions depend on the material and use, this information will be included in the EFPIA final submission. |
| Answer to specific info request 6:  - EU API that are PFAS by definition, and downstream products containing them (medicinal products) as derogated in restriction option - development products under product and process orientated research and development for API that are covered by the PFAS definition, and downstream products containing them (medicinal products); their manufacturing, medicinal product manufacture and application (e.g., clinical testing) non-active ingredients (excipients) - excipients in pharmaceutical products containing PFAS residues - fluoropolymers in production equipment (reactor lining, seals, gaskets, piping, anti-stick coating, surfaces, filtration units etc.) This is particularly true for sterile and aseptic production processes, as some high-molecular-weight API substances can only be safely filtered sterile with PFAS membranes, and alternatives are excluded due to material properties (instability at high temperatures, interaction and binding with alternative filter membranes). - fluoropolymers with product contact and quality impact, including spare or replacement parts druck und temperaturstabil sowie inert PFAS consumables and single-use material (filters, bags, tubes, etc.) - fluoropolymers in complex equipment, such as insulation material, mechanical parts, including spare or replacement parts - analytical laboratory equipment, e.g., Teflon tubing, valves, gaskets, filters raw and starting materials, chemical intermediates, reagents, solvents, auxiliaries in manufacturing including storage and transport, quality control - PFAS materials and reagents used in quality control activities mandated by product licenses or regulations such as European Pharmacopoeia monographs - PFAS other than fluoropolymers in equipment, such as electrical components, diagnostic laboratory testing, refrigerants in laboratory equipment such as temperature-controlled centrifuges - immediate packaging of medicinal products and API’s such as containers or closures with product contact, using approved fluoropolymer materials or coatings such as PCTFE, ETFE or PTFE, applies to blisters, sachets, tubes or other metal or plastic containers, vial stoppers or other coated elastomers packaging containing fluoropolymer film for the protection of medicinal products or medical devices from air, moisture, other contaminants or to maintain sterility or stability - fluoropolymer substances used in the functioning and components of devices used in single integral medicinal products regulated by Medicinal Product Directive 2001/83/EC, and EU MDR 2017/745 Annex I |
| Answer to specific info request 7:  As socio-economic impact and potential alternatives depend on material and use, this information will be included in the final EFPIA submission. |
| Answer to specific info request 8:  Although the pharmaceutical industry was granted a time-unlimited derogation for the specific use of active substances used in human medicinal products in the EU, the sector was not identified in the restriction, including Table 8 and Table 9. Derogations for substances which do not cover their manufacture and development in Europe will initiate relocation outside of Europe. The current European share of global pharmaceutical revenue is 23.4%, and the estimated research and development spending is 41.5 bn Euro (2021, statista.com). A socio-economic impact analysis is prepared through EPPA (www.eppa.com) and will be provided in due course of the consultation, to substantiate the consequences of the proposed restriction on the pharmaceutical industry and the availability of medicines. |

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| 5965 | Date:  2023/06/29 14:28  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:  Tycker begränsningsförslaget är bra som det är. För mig är det viktigtatt stoppautsläpp av långlivade kemikalier. Gör inget om regnkläder blir något sämre eller mobiler lite större |

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| 5966 | Date:  2023/06/29 15:05  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Kiilto Oy  Org. country:  Finland  Attachment:  <redacted> | General Comments:  The restriction does not take into account the condition or how likely the PFAS compound ends up in nature or humans. It is a different matter to process industrial components or coatings in the chemical industry than to use in general consumption items such as textiles as a water-repellent coating that wears off in the wash or ends up directly on human skin |
| Answer to specific info request 1:  Chemical industry, manufacturing adhesives and sealants |
| Answer to specific info request 3:  From the industrial use waste is handled with care and proprier way. There are minimum risk to end up PFAS components to nature. |
| Answer to specific info request 6:  Attached excell of usage PFAS components in one chemical factory in Finland |

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| 5967 | Date:  2023/06/29 15:25  Type:  Individual  Country:  Sweden | General Comments:  I don't see any reason at all to let human beings living now or coming generations to be exposed to all the danger and harm we know that PFAS has on our environment and bodies. There are other options. |

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| 5968 | Date:  2023/06/29 15:50  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, att det ska behållas som det är och att det kommer att antas utan att urvattnas. Det är viktigt att vi inom EU ser till att stoppa utsläpp av långlivade kemikalier, även om det skulle leda till försämrade egenskaper för vissa varor om PFAS kan slut användas. |

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| 5969 | Date:  2023/06/29 16:17  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  WEYLCHEM Lamotte  Org. country:  France  Attachment: | General Comments:  We submit a document in which the relevant topics are adressed |
| Answer to specific info request 2:  We submit a document in which the relevant topics are adressed |
| Answer to specific info request 3:  We submit a document in which the relevant topics are adressed |
| Answer to specific info request 5:  We submit a document in which the relevant topics are adressed |
| Answer to specific info request 6:  We submit a document in which the relevant topics are adressed |

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| 5970 | Date:  2023/06/29 17:26  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Sweden  Company name confidential:  Yes  Attachment: | General Comments:  Given the number of missing uses impacting the Life Sciences and Biopharma industries, the 9000 character limit was insufficient to fully comment on the impact of the PFAS restriction, instead all comments are given as an attachment using the format of the comment, additional input will be provided as more data is being developed.  The current analysis and proposal do not proportionally address the high industry impact on the life sciences and biopharmaceutical sectors. This initial response seeks to outline the high industry concern and key missing uses; we will also submit a further response with detailed data on the costs and impact to our industry by the consultation deadline to further inform ECHA’s assessments. This response: ▪ Requests a 6 month extension to the consultation period to collect and provide data on the impact on the life sciences and biopharmaceutical sectors and the socio-economic risks this restriction poses to industries and their downstream users, including patients. ▪ Requests that fluoropolymers be excluded from the scope of the restriction; ▪ Requests that the critical equipment used to fabricate pharmaceutical and biopharmaceutical products be recognized as missing uses and proportionate derogations be considered; ▪ Responds to specific information request for the following 5 missing uses: o [1] Hydrophobic and/or Oleophobic Filtration Membranes in Pharmaceutical Processing o [2] Fluoropolymer-based bioprocessing materials (e.g. membranes, gaskets, seals, fittings, etc.) in which no PFAS (C16 and lower) chemicals or processing aids are used to manufacture the polymer o [3] Fluoropolymer-based bioprocessing materials (e.g. membranes, gaskets, seals, tubing, O-rings, pumps, connectors) in which PFAS-processing aides may be used in the manufacture of the polymer. (e.g. PTFE filtration membranes, gaskets, seals, etc.) o [4] Fluoropolymer used as auxiliaries on sites to manufacture chemicals vital to the bioprocessing industry o [5] Membranes used in medical device-related applications, including oleophobic, PTFE, and PVDF |
| Answer to specific info request 1:  See attachment |
| Answer to specific info request 2:  See attachment |
| Answer to specific info request 3:  See attachment |
| Answer to specific info request 6:  See attachment |