**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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| 8134 | Date:  2023/09/21 09:51  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Japan Business Machine and Information System Industries Association (JBMIA)  Org. country:  Japan  Attachment: | General Comments:  Japan Business Machine and Information System Industries Association (JBMIA) is pleased to provide the comments to the Consultation on PFAS in Annex XV of the REACH Regulation. JBMIA is a Japanese industry association of information and communications technology sector composed of twenty one member companies including more than ten global “imaging equipment such as printer and copier” manufacturers. With regard to the scope of application, it is almost impossible to deal with the current proposed regulations because of the limitations of information transmission through the long and complicated supply chain, especially for articles. Of the 10,000 PFASs that are said to exist, if only those with particular hazards are designated as SVHCs, they can be managed in the current supply chain, and 1000ppm can be controlled. Our member companies are assembly manufacturers and also deal with consumables such as toner. Proposed thresholds of 25 parts per billion (ppb) and 50 parts per million (ppm) for chemicals are extremely difficult and almost impracticable for downstream users like us to control. We explain the reasons by using illustrations in detail why PFAS is necessary for key parts of printer and copier in Attachment 1. In terms of hazard or exposure, we believe that some of the 10,000 PFASs do not meet the Persistent or Bioaccumulation criteria, and we have a serious concern that substances only having Persistent or Bioaccumulation alone are regarded as a hazard that should be regulated. Emissions into the environment are only the estimates because we do not have any specific information, but we will describe in Section 5 of the specific information request. We explain the essential use of PFAS in the printing and copying processes in detail in specific information request 6. Some key components used in copiers and printers are required to surely fulfil at a high level, all characteristics of heat resistance, releasability, flame resistance, flexibility, water and oil repellency, and wear resistance, and it is almost impossible to substitute them. In terms of socio-economic impacts, if PFAS were to be regulated as proposed, we would not be able to substantially produce printers and copiers. This would not only affect our original manufacturers, but also would have far-reaching negative impacts on component and raw material manufacturers. Also, we think that copiers and printers are essential products in the social economy, and the negative impact on users will be enormous if these machines cannot be produced and marketed. We describe exemptions in detail in specific information request 6. We currently have no way and method for phase out PFAS used for some key components, we think that a very small amount of PFAS used for the key component will not have a large impact on the environment after the end of the product's life. Therefore, we would like to request exemptions for non-replaceable and essential uses of PFAS for printing and copying processes. Even if we address to replace PFAS into alternative materials for other key components, it will take a long time for development of alternative materials to fulfil all of characteristics required in printing and copying processes, and we would request “time-unlimited for duration of derogation” or “at least 12 years duration”. We explain the reasons by using illustrations in detail why it will take a long time to substitute PFAS in developing process of printer and copier in Attachment 2. |
| Answer to specific info request 1:  Sector: Electronics Sub-Use: Copier/printer (fixing-related unit, photoconductor, intermediate transfer belt, grease, etc.) Type of PFAS: Fluoropolymers (PTFE, PFA, PVF, etc), Fluoro oil (PFPE etc), Anti-dripping agent in flame retardant resin, fluorine-containing additives, etc. |
| Answer to specific info request 2:  There is no manufacturing process in which PFAS are regularly disposed of in the form of by-products or losses during manufacturing. In some models, a small amount is added to the developer, so the amount fixed on the paper and discharged amount is not zero. However, since it is only printed on paper, it is not directly discharged into the environment as PFAS. |
| Answer to specific info request 3:  In the first place, the amount of fluororesin used in electronics is small, and end of life EEEs are subject to EU WEEE Directive. We think that end-of-life EEE have been collected and recycled / dispositioned appropriately in accordance with the Directive. We think that the use of PFAS in electronics has less impact on the environment. If there are concerns about PFAS in waste EEE, we believe that it can be effectively managed by strengthening the management of separate processing and treatment facilities through recycling and waste laws such as the WEEE Directive, rather than by regulating them under the REACH Regulation. In addition, the reduced environmental impact of reducing PFAS in electronics will be small compared to the increased waste generated by substitution. Fluorine-based materials have both high functionality, high durability, and high stability, resulting in long life and low waste volume. Even if PFAS could be reduced, the environmental impact would increase in other aspects, because the reduction of PFAS would increase waste. |
| Answer to specific info request 6:  a) Types of PFAS include PTFE, PFA, PVF, other polymers, and PFPE (lubricant). Emissions are listed in Specific Information Request 5. b) We describe electrophotography briefly before detailed explanation of the main functions. See Attachment 1. In the electrophotography, a printed material is produced by transferring/fixing toner particles to paper. Toners are composed of pigments and polymers etc. After the toner particles are electrostatically attached to the latent image formed on the photoconductor, they are electrostatically transferred to the paper directly or if necessary via an intermediate transfer medium, and then heat and pressure are applied by a heating/pressurizing components (Roller, belt) to fix the toner particles to the paper. Since a printer/copier is required to print different characters/images tens of millions of times, the next printing cannot be performed properly even if a very small quantity of toner residue remains on the photoconductor, transfer belt, and fixing components. Fluorine-based materials are used in these parts. Fluorine-based materials are also used in various other parts, such as separation claws (separating paper from its members), gears, bearings, grease, and end sealing members. Fluorine-based materials used in these components must simultaneously satisfy a number of characteristics, such as excellent releasability, heat resistance, chemical stability, abrasion resistance, flame retardancy, and flexibility. In particular, the fixing components are required to fix the toner melted at high temperature by applying pressure to the paper. At the same time, it is also required that the image produced by the melted toner is peeled off from the fixing components without any omission of the original image data. Therefore, it is necessary for the components to satisfy almost all of the characteristics mentioned above in the temperature range of about 150-250 degrees Celsius at the same time, and there is currently no substitute material. c) There are only a few dozen of imaging equipment manufacturers. However, if the use of PFAS is prohibited as proposed, the production of copiers/printers will not be possible. At the same time, a wide range of parts and raw material suppliers will be affected. In addition, we think that copiers/printers are an essential product in the social economy, and if they become unavailable due to the PFAS ban, all companies, government offices and individuals using printers and copiers will be affected. In other words, the impact will be widespread in the worldwide beyond the EU. d) In an electrophotographic printer/copier, there is no substitute material because the fixing components cannot be made without PFAS. On the other hand, there may be alternatives in other type of printing process, but parts may be less durable and replaced more frequently. Also, as mentioned in c), many of the printing products that are already part of the social infrastructure will not be able to be sold, so there may be a shortage of alternative products as mentioned in the question. e) In the search for alternative materials, it is required that they have the same characteristics as PFAS, such as deformability, flame retardancy, chemical stability, wear resistance, etc. In addition, it is necessary to select materials that do not fall under the persistent nature regarded as the proposed PFAS regulatory basis, and there is currently no substitute material. At present, we do not know any materials to fulfil heat-resistant and non-adhesive functions at the same time, and for example, even a Silicone polymer system which claims releasability / heat resistance is insufficient. In addition, although several decades have passed since consideration of the substitution of fluoropolymer for sliding property, no alternative substance other than fluoropolymer has yet been found. In order to actually apply it to products such as printers and copiers, it is necessary to examine the processing conditions for the parts and to meet many evaluation criteria such as strict image quality, durability, and safety for each printer and copier, and it is necessary to re-acquire various safety standards and environmental certifications for each printer and copier in accordance with the change of components. Some manufacturers produce and sell hundreds of different printers and copiers with different printing speeds and functions to meet various customers’ demands, and it is impossible to develop, evaluate, and obtain certifications for all printers and copiers at the same time, so even if alternative materials are found in the future, it is impossible to replace all products with alternative materials in 12 years (see Attachment 2). In addition, considering that each country's PL law under Council Directive 85/374/EEC (Product Liability Directive) imposes product liability for 10 years, service parts must be supplied to customers who purchase copiers and printers for at least 10 years. In view of the above, we have no choice but to request the “time-unlimited for duration of derogation” or “at least 12 years duration”. f) i. There are currently no alternatives, so costs cannot be calculated. ii. Even if there is an alternative in the future, it will simply take at least 12 years (This includes several years for the investigation of alternative materials, five years for development, and a warranty period for service parts.) iii. When less durable materials are used, the user frequently needs to replace/repair parts, and the burden of replacement/repair costs becomes enormous. iv. No alternative provider information available. g) As mentioned above, the loss of printers and copiers, which are already part of the social infrastructure, will affect everyone in the EU. In addition, for businesses that use printed matters as their products, the deterioration of image quality will increase the number of unsuitable printed matters, which will significantly reduce profits and cause problems such as delay in delivery. |
| Answer to specific info request 8:  We considered the economic loss and social impact of the inability to produce electrophotographic copiers/printers due to PFAS restrictions. The statistics currently available from JBMIA do not accurately calculate volumes of printer and copier in the EU market, but the economic impact would be equivalent to billions of Euros in annual sales in the EU, and the losses would have a direct impact on related supply chains in Europe. In other words, not only we, original manufacturers, suffer losses, but the people and companies involved in the supply chain in the EU are also likely to suffer losses. Furthermore, there are likely to be tens to hundreds of millions of existing copiers/printers already on the market in the EU. If PFAS were to be completely restricted, maintenance and service parts would be unavailable before the end of the copier/printer's life. Even working copier/printer can become a waste soon if it runs out of maintenance parts. The environmental impact of the increase in waste is a concern. |

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| 8135 | Date:  2023/09/21 09:58  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sang-A Frontec  Org. country:  Korea, Republic of | General Comments:  SANG-A FRONTEC CO., LTD is a Korea-based company that specializes in processing with fluororesins. We request to be completely excluded from ECHA's PFAS restrictions such as sealing for home appliance compressors using fluororesin.  Consumption of all PTFE types worldwide and in Western Europe is 190 million and 35 million. PTFE is a high-performance polymer with unique properties. Provides temperature range from -250°C to +260°C, general purpose chemical resistance, hydrophobic properties, excellent dielectric properties, etc. It is a very valuable material for use in various industries.  For fluororesins, there are more evidence that there is no negative impact on humans and the environment during the stages of use (such as approval of food contact, approval of drinking water contact, etc.) if there is a risk at the end of the manufacturing process and life. A complete ban on PFAS (including fluoropolymers) means deindustrialization of Europe. Because fluoropolymers are needed along the entire supply chain of many industrial sectors. Safety aspects (pumped media can injure people) require fluoropolymers from the start of the supply chain to the production of basic chemicals, starting from the beginning of the material manufacturing process (polymer part molding), parts (electronic manufacturing) and products (fluoropolymers that are part of the mechanical equipment that produces the product) for a number of other reasons. High-performance technologies require high-performance materials. Renewable energy, which should also be used in industry, can only be used for fluororesins. The development of new technology (in some cases) requires that kind of material that makes the impossible possible with other materials.  It is also important to consider other regulations required to bring the product to market if all PFAS are prohibited (e.g. energy efficiency, hygiene requirements, ATEX, food contact, drinking water contact…) cannot be prohibited. It is no longer implemented for a specific product. Generally, PFAS is used in very small amounts only when it is actually needed, and in most cases, other (cheap solutions) performance is excellent. Safety aspects (pumped media can injure people) require fluoropolymers from the start of the supply chain to the production of basic chemicals, starting from the beginning of the material manufacturing process (polymer part molding), parts (electronic manufacturing) and products (fluoropolymers that are part of the mechanical equipment that produces the product) for a number of other reasons. High-performance technologies require high-performance materials. Renewable energy, which should also be used in industry, can only be used for fluororesins. The development of new technology (in some cases) requires that kind of material that makes the impossible possible with other materials. Excluding fluororesin products from home appliances necessary for daily life may cause poor performance of products such as refrigerators, air conditioner compressors, microwaves, and ovens, especially if fluororesin products are not applied to refrigerator compressors, we may not receive fresh food and cause fatal problems to the human body. Generally, PFAS is used in very small amounts only when it is actually needed, and in most cases, other (cheap solutions) performance is excellent. Therefore, I think it is very unreasonable to limit fluororesin products applied to fluororesin polymers and automobile gaskets, sealing, etc. |
| Answer to specific info request 6:  Fluoropolymers (PTFE, FKM, FFKM, FPE, (PFPE), ETFE, ECTFE, PVDF, PFA, PCTFE) are used in SEAL, GSKET, diaphragm DIAPHRAM, cable, COATING, abrasion parts, BEARING, etc., and can be more resistant and safe against chemicals, friction, temperature, weather, or combinations thereof, ensuring better energy efficiency, longer lifespan, and improved safety.Compared to normal material use, it is significantly effective in terms of cost and environmental protection because it can be used for a long time without compromising performance, reducing the number of maintenance and preventing |
| Answer to specific info request 7:  \* a compressor in the field of home appliances - Application: GASKET, SEAL, Wear Parts. - Properties: Resistance to hydrocarbons, heat resistance, low coefficient of friction, corrosion resistance and abrasion protection properties (PTFE, ETFE) \* Food Industrial Pumps - Application: COATING, SEAL, - Characteristics: Enhancement of SEAL, GASKET, DIAPHRAM DRAM, Cable, COATING, Wear Parts, BEARING functions - Improve resistance to chemicals, temperatures, weather, or combinations thereof, and safety. - Used due to frictional engineering functions. Leads to better energy efficiency, longer life, and improved safety. - Use due to hygiene aspects; Health Protection Electronics Industry: as a supplier to the pump industry, this sector is of great importance. Without electronics, efficient pumps cannot be manufactured. PFAS (primarily fluoropolymer) is used in semiconductor production or as a material for parts. |

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| 8136 | Date:  2023/09/21 10:02  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sumitomo Electric Fine Polimer, Inc.  Org. country:  Japan | General Comments:  European Chemicals Agency P.O. Box 400, FI-00121 Helsinki, Finland 　　　　　　　　　　　　　　　　　　　　　　　 Sumitomo Electric Fine Polymer, Inc.  Comments on Annex XV Restriction Report (PFAS Restriction Proposal)  Our company group pushed forward business along Sumitomo business spirit since its formation. For the Sumitomo electric group corporate principles that stipulated Sumitomo business spirit, it prescribes the text "contribute to creating a better society and environment, with firm awareness of our social responsibility" as a guideline for society and environment. We coped and contributed to society and environment along these regulations. Therefore, for the PFAS regulation that ECHA insists on, I will act to contribute to social and environmental improvement. In addition, in consideration of benefit in the economic and environmental whole of PFAS of the present, we apply for "exemption" targeting at "the fluoric resin (PFAS) use with the toner fixation roller in the printing product such as Copy-machine" until hazardousness of applicable PFAS becomes clear.  The application grounds are following three points. ①Concern of environmental load expansion and the substitute materials development delay by the extensive PFAS regulation at the stage when hazardousness is uncertain, ②Detoxification by the emission management in Life-cycle of the printing product, ③Substitute difficulty of the fluoric resin with the extremely low surface energy properties  ①The fluoric resin became the materials of various apparatuses by the superior characteristic. In the toner fixation roller loaded into the printing product, fluoric resin such as PFA is used for the roller outer layer materials. By utilizing mold releasability and heat resistance of the fluoric resin, speed-up and high-definition, low power, expendable supplies reduction, apparatus compactification in the printer is realized. These effects contributed not only to market expansion and price reduction, but also to environment load reduction such as waste reduction and resource saving, energy saving ,CO2 emission reduction. For example, the fluoric resin is used as a required technique in order to achieve an "eco-design order" standard with the printer to sell in EU area. The use of the superior PFAS's performance useful for the environment is inhinbited, when we regulate the material, such as PFA, which hazardousness is not established uniformly. In this way, there is concern to let, on the contrary, you enlarge environmental load when the performance of PFAS substitute materials is inferior to that of conventional PFAS. When we regulate only the noxious material, the material targeted for development is narrowed down in the substitute materials development. By concentrating labor force committed, we can accelerate alternative technology development. On the other hand, when we regulate a wide range of material called the overall PFAS which ECHA insists on, the object of the technology development spreads, and material resources invested disperse, and there is concern to delay substitute time.  ②The hazardousness of PFAS to the human body and a living thing is uncertain at the present. However, we understand the claim of ECHA that PFAS is suspected of the toxic substance. While at the waste disposal treatment of the printer apparatus in the EU area, inning or incinerating process is carried out under the strict environmental regulation. For the concern of ECHA, we suggest that we can detoxify the toxic substance by enforcement of the above waste disposal treatment.  ③The fluoric resin is material of the lowest surface energy, therefore the mold release characteristics for the print toner is superior, and the printing product by the current electron exposure method is developed. We realized the printing system of high-speed and high-definition, low electric power by using fluoric resin. This style of printing system based on the low surface energy properties of the fluoric resin is improved aiming for the high heat conduction and compactification. After invention of the fluoric resin, the progress of the material development is remarkable, but the materials with the surface energy properties of the fluoric resin equivalency are not still invented.  We understand concern of ECHA to hazardousness of PFAS. However, in consideration of above-mentioned three points, we think that it is rational to contribute to economy and environment by utilizing PFAS, until hazardousness of each PFAS is confirmed. In our associated "fluoric resin (PFAS) use with the toner fixation roller in the printing product such as Copy-machine", we apply for "exemption".  Sincerely yours,  Yoshimasa Suzuki President Sumitomo Electric Fine Polymer, Inc. |
| Answer to specific info request 1:  ＜Annex XV（P54）　Table2　：PFAS main applications and sub-uses.＞ Main applications :Electronics and semiconductors Sub-uses :Electronis components、Photolithography ＜Annex A(P108)　Table A.48. Uses and properties of PFASs in the electronics industry identified by stakeholders.＞ Use category :Electronis components Sub-use :Others Area of use/applications :・・・・, copy machine, ・・・・ Copy-machine and Printer utilizing the electronic exposure technology that is a part of Photolithography are sold by the electronic equipment manufacturer, and are used to make the document in the companies desk work section.The print process in the printer mentioned above puts various units (Electronis components) including the electronic exposure unit together to print a toner on the paper clearly. The toner fixation roller which used the fluoric resin superior in mold release characteristics and heat resistance is put on a fixation unit. he target product by this application is a toner fixation roller of the fluoric resin outer layer utilizing mold release characteristics and the heat resistance of the fluoric resin. The fluoric resin (PFAS) to use for the outer layer of the roller mentioned above is PFA and PTFE, FEP. By being equipped with this fluoric resin outer layer fixation roller, we realize speedup and high-definition, low-power, expendable supplies reduction, apparatus compactification in the printing. |

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| 8137 | Date:  2023/09/21 10:07  Content:  Hazard or exposure  Environmental emissions  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  We would like to explain the hazard information regarding fluorinated gas used as SF6 alternative for molten magnesium cover gas. This fluorinated gas CAS No. is 756-13-8 (chemical name: 1,1,1,2,2,4,5,5,5-Nonafluoro-4-(trifluoromethyl)-3-pentanone) and has a boiling point of 40℃. This fluorinated gas is produced by various manufacturers including 3M (Novec612), Zhejiang Noah Fluorochemical (Noah5112), Fanda Chemical (FK649), and Waysmos (FK 5-1-12). Based on OECD301B biodegradation test, 1,1,1,2,2,4,5,5,5-Nonafluoro-4-(trifluoromethyl)-3-pentanone is not readily biodegradable as the amount of CO2 generated biologically within 28 days was calculated to be 3%. Regarding atmospheric degradation, 1,1,1,2,2,4,5,5,5-Nonafluoro-4-(trifluoromethyl)-3-pentanone reacts with OH radicals, and the half-life in the air is estimated to be 5.11 days, with a Global Warming Potential (GWP) of less than 1. For bioaccumulation, 1,1,1,2,2,4,5,5,5-Nonafluoro-4-(trifluoromethyl)-3-pentanone was tested under OECD305 procedure, and was found to have a very low concentration, below 4.8. On the other hand, this gas decomposes under ultraviolet light, producing TFA and HF in the process. Mutagenicity was assessed using the AMES test, and no mutagenicity was observed. Acute toxicity evaluation involved exposing rats to vapor of 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone for 4 hours, resulting in an LC50 of more than 1,227 mg/L, and an LD50 of more than 5,000 mg/kg in oral ingestion, making it a safe liquid.  [Request for Exemption] 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone is used as a fire-resistant cover gas when casting magnesium alloys. Magnesium is the lightest among practical metals, and it has higher specific strength and specific stiffness compared to aluminum, iron, and plastic materials. Therefore, it is applied to the casings of mobile phones and laptops, and it is expected to expand its application to automotive components where weight reduction is required, such as electric vehicles in the future. Moreover, it is recyclable, and the energy required for recycling is only 4% of that for new block manufacturing, making it an eco-friendly material.  However, molten magnesium burns with a flash when it reacts with air, so 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone and a mixture of CO2 or N2 are supplied as a cover gas to the surface of molten magnesium to form a protective film and prevent combustion. While some regions use SO2 as a cover gas, SO2 pollution in the atmosphere can irritate the respiratory system and lead to disorders such as coughing, asthma, and bronchitis. The Minamata disease, which occurred around 1961 in Japan, is a famous example of the health hazards caused by SO2, making it a challenging substance to use in Japan. The SO2 environmental standards require a daily average of 0.04 ppm or less for a one-hour value, and 0.1 ppm or less for a one-hour value. When SO2 is used as a cover gas, it is highly likely to leak out of the magnesium dissolution furnace, posing significant risks to workers.  In contrast, 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone is non-flammable, low in toxicity, has a GWP of 1. Furthermore, the Ozone Depletion Potential (ODP) of 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone is 0, indicating that it does not contribute negatively to environmental issues such as ozone depletion or global warming.  Based on all the hazard information provided, 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone is assumed to be a cover gas that is friendly to both health and the environment thus we strongly request 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone to be exempted from PFAS regulations.  We believe that regulatory targets should be limited to substances where a risk assessment based on scientific evidence recognizes an impact on human health or the environment, taking into consideration economic and societal impacts and kindly ask ECHA to reconsider 1,1,1,2,2,4,5,5,5-nonofluoro-4-(trifluoromethyl)-3-pentanone from restriction target. |
| Answer to specific info request 1:  Metal plating and manufacture of metal products, magnesium casting |

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| 8138 | Date:  2023/09/21 10:07  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sang-A Frontec  Org. country:  Korea, Republic of | General Comments:  SANG-A FRONTEC CO., LTD is a Korea-based company that specializes in processing with fluororesin. We request that medical PTFEE TUBE using fluororesin be completely excluded from ECHA's PFAS restrictions. SANG-A FRONTEC CO., LTD., a producer of fluororesin tube, including PTFE for medical devices, requests a general PTFE regulatory exemption. PTFE Paste Extruded Products (fluororesins) These products allow hundreds of thousands of workers in industries such as chemical process industries, pharmaceuticals, healthcare, drinking water, food, energy, renewable energy, automobiles, etc. to produce products and generate billions of euros or more in sales in Europe. It shows that fluoropolymer is not a risk to the health and environment of the worker. The industry and its alternative materials mentioned above are very limited, and the fluoropolymer prohibition may cause factories and companies to be relocated to countries outside Europe. This results in the loss of hundreds of thousands of jobs in Europe, billions of euros in sales, and with all the known impacts, a greater reliance on products outside of Europe. PTFE tubes and catheters used as medical devices are disposable devices and are biologically hazardous waste after being used for stent implantation. It's being incinerated after use. PTFE is essentially converted to carbon dioxide and hydrogen fluoride and converted to non-toxic fluorescent in the filter system. Therefore, there is no emission at the manufacturing stage (using semi-finished PTFE parts), and there is no emission at the use stage and the end of life stage. |
| Answer to specific info request 6:  For all segments (including sub-use), SANG-A FRONTEC CO., LTD is affected by the segments mentioned in Survey 1 and uses only PTFE, with the main functions of PTFE as follows: • Proven biocompatibility of PTFE and ePTFE implants for long-term use in vascular implants • Long-term evidence of safe clinical use in implant applications • Very high plastic strain at low polymer stiffness low stress values • Durability and chemical stability in poor environments • Low coefficient of friction • Material expansion capability (ePTFE manufactured in fiber structure) • Semi-permeable (up to expansion) while maintaining fluid/blood adhesion Many medical devices require ePTFE or PTFE. Therefore, many healthcare companies, vendors, and customers (mainly hospitals) are concerned about PFAS restrictions. According to PTFE and ePTFE suppliers and research institutes, an alternative is not expected in the near future. In general, it is unclear whether alternatives will come out. Since there is no alternative yet, research on innovative new materials will take a lot of time. Approval of the substance and subsequent product development (including clinical research) takes more than 13.5 years. For comparison: Development with known materials now takes more than seven years. All approved products include ePTFE covers, so no alternative is available after 12 years of total prohibition. Therefore, the quality of medical care deteriorates. The number of employees cannot be estimated because medical companies, suppliers, and customers (mainly hospitals) are concerned about PFAS restrictions. |

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| 8139 | Date:  2023/09/21 10:10  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Because it contains the company's own confidential information | General Comments:  We supply films using fluorine raw materials, such as PTFE, according to the customers' applications. Fluoropolymers have various characteristics and functions, they are used in a wide range of applications in various industries. We supply the most suitable processed fluoropolymer products for many different applications. Regarding the European PFAS regulation proposal, we understands that it is being proposed in consideration of the environmental impact and the impact on the human body in order to create a sustainable future and the company sympathizes with that way of thinking. There are several uses that would affect the European society and economy if they are restricted without any alternatives.  In this section, we would like to provide our opinions on industrial masks used in mines, factories, and other environments with a lot of dust, and special masks used by the police, fire department, military, etc., during emergency rescue operations.  PTFE porous membranes are generally used as filter materials for masks used in the above applications. There are non-woven cloths (including electret non-woven cloths) and glass filter materials that can be used as materials for masks. However, high air permeability and high collection performance are required for the material and only PTFE porous membranes can satisfy those functions. Please refer to the file attached to Section V ("High-function mask") for detailed information on the comparison of PTFE porous membrane and other materials for this application. If the materials other than PTFE porous membrane are used for this application, the filter will not be able to stop the dust sufficiently and may cause inhalation of hazardous substances. In addition, if we try to increase the collection efficiency, the air permeability will be reduced and we will not be able to breathe as much as we would like. Therefore, we ask for unlimited derogation for these specific applications. |
| Answer to specific info request 1:  〇Sectors and uses　：　Professional apparel (incliding PPE) \*Just in case, section 6 is also listed. 〇Usage：　Industrial mask and special mask |
| Answer to specific info request 6:  (6a): 〇PFAS name：PTFE 〇Annual usage：0.2t/year 〇Annual emissions：I don't have information on this topic (6b): 〇Please refer to the document "High-function mask" attached in Section V. (6d): 〇Information on alternative materials and data comparison is attached in Section V; document name: "High-function mask". 〇 PTFE has a large molecular weight so it basically does not react or accumulate in the body. In addition, fluoropolymers meet the criteria of "Polymers of Low Concern" of the Organization for Economic Cooperation and Development (OECD). 〇A report on the toxicity of PTFE exists and is attached to Section V under the file name "Reference material 1" as evidence that PTFE is a material of low concern. (6e): 〇There is no other material with the same performance as PTFE(PTFE porous membrane). Therefore, it is not possible to estimate the excepted time required for substitution. (6f): 〇No available information on alternative materials at this time. |
| Answer to specific info request 7:  If masks using PTFE porous membrane are restricted, many companies and institutions such as PTFE raw material manufacturers, PTFE porous membrane processing manufacturers, mask processing manufacturers, and institutions in Europe that require masks using PTFE porous membrane will be affected. As we have approximately 50 employees involved, there could be employment-related impacts. |

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| 8140 | Date:  2023/09/21 10:10  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The included information may provide competitors confidential information about the market position and manufacturing technology. | General Comments:  The commenting company is a downstream user of chemicals, its products are articles in the sense of REACh. The commenting company relies on information from suppliers with respect to the content of PFAS in the supplied materials and does not have its own detailed knowledge of the need for PFAS in materials. In principle, due to the breadth of the restriction proposal, it is unclear in which materials, applications which and how many PFAS are used. Even after multiple requests, the commenting company does not get answers from some material suppliers about the used PFAS. There is no legal obligation to provide information according to CLP-Regulation, and since most PFAS are not classified as hazardous substances or are below a notification threshold the PFAS shall not be declared in safety data sheets. The use of PFAS is treated as intellectual property of the chemical or material supplier, so the identification of the specific substance is not communicated to customers as companies need to ensure that their investment is protected.  The commenting company supports the EU's goal to avoid the emission of PFAS into the environment and to prohibit substances where substitutes exist or will soon exist. The commenting company appreciates, if the EU can introduce a reporting requirement to ensure sufficient data on use along the supply chain and restrict PFAS only in areas where there is a real risk from PFAS. That means that the commenting company supports the risk-based substance approach, i.e., the use of PFAS must continue to be allowed in applications where the risk is manageable or no suitable substitutes are available and emissions in the environment can be minimized.  Basically, we see the risk that due to the rigid factual and time requirements and due to the complexity of the supply chains, derogations for relevant uses can be missed and subsequently no longer granted. |
| Answer to specific info request 1:  Use sector: Electronics and semiconductor (Annex E.2.11.) Sub-use: Semiconductors, Electronic components, coating, Advanced semiconductor packaging, photolithography |
| Answer to specific info request 2:  see PFAS\_consultation\_confidential.pdf |
| Answer to specific info request 3:  see PFAS\_consultation\_confidential.pdf |
| Answer to specific info request 7:  see PFAS\_consultation\_confidential.pdf |

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| 8141 | Date:  2023/09/21 10:16  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sang-A Frontec  Org. country:  Korea, Republic of | General Comments:  SANG-A FRONTEC CO., LTD is a Korea-based company that specializes in processing with fluororesin. We request that automobiles using fluororesin such as sealing and tubes be completely excluded from ECHA's PFAS restrictions.  · Engine equipment such as passenger cars, trucks, bases, motorcycles, lawnmowers, ships, airplanes, etc. have many parts made of fluoride rubber and fluoride plastics. The energy of these engines is primarily gasoline or diesel. Recent gasoline and diesel include alcohol, MTBE, etc. for environmental efficiency. Fluorinated rubbers and fluoroplastics are highly resistant to gasoline, diesel, alcohol, MTBE, etc. Therefore, many fuel system parts are made from fluorinated rubber and plastics. · Previously, fuel system parts were made of NBR rubber or metal. However, there are several problems in this area : photochemical oxidants. One of the causes of this problem was the evaporated gas from the vehicle. Although many NBR rubber parts have been used in fuel systems, the NBR does not have sufficient fuel gas permeability. Fluorine rubber or fluoride plastic has a very good permeability of 100 times or more, so we use fluoride rubber or plastic as a countermeasure. ･ Of course, metal penetration is better. However, metal is much heavier than rubber or plastic, which results in poor fuel efficiency. The engine also has vibrations and requires flexible parts at the connection. The strength of the carbon-fluorine bond and the polymer structure of these polymers are unmatched. In the years since its development in the 1950s, it has not succeeded in finding alternative materials that can replace or improve performance for nearly 70 years. There are no technical alternatives available for fluoropolymerization in all applications. In the near future, e-fuel and/or biomass-made fuels should be used commercially. This should include chemicals similar to gasoline, diesel, ethanol, etc. Therefore, the fuel system of the engine needs fluorine rubber and fluorine plastic, so we ask for an exemption. |
| Answer to specific info request 1:  Engine fuel system parts: application of passenger cars, motorcycles, lawnmowers, ships, planes, etc. |
| Answer to specific info request 6:  For fluorinated rubber and fluorinated plastic gaskets, there is no alternative material to provide an essential combination of chemical resistance, heat resistance, compression and non-polluting properties. Gasket for sealing chemicals and corrosive fluids requires chemical resistance and purity that does not contaminate chemicals. In addition, proper compression properties are required to maintain confidentiality. Fluororesins are flexible and can be used at low clamping pressures, which are essential for stable sealing of these fluids. Currently, there is no material other than fluororesin that has these characteristics. Chemical resistance cannot be satisfied with a joint sheet in which inorganic fibers or organic fibers are bound with a binder. For example, chemicals such as aqua, perchloric acid, chromic acid, chromic acid, chromic acid, hydrobromic acid, nitric acid, hydrofluoric acid, and bromine cannot be used in conventional joint sheets, and these fluids are highly corrosive. Leaks have a huge impact on people and the environment. Therefore, these seals require a reliable gasket. Rubber gasket is also used, but it is less chemical resistant than fluorine resin, and silicone rubber with heat resistance and chemical resistance is not enough to replace. The relatively chemical resistant graphite sheet is fragile and can contaminate the chemicals (gas, liquids) used in the application. Metal and semi-metal gaskets are less chemical resistant and require excessive load when tightened, and cannot be handled by conventional flanges due to strength. It is expensive to review the design specifications of the piping part of the equipment. Heat-resistant PEEK materials and low-friction ultra-high molecular weight PE can be considered as packaging materials, but they have disadvantages of lack of flexibility, poor sealing performance, and are also expensive materials. It's too expensive and less practical. Additional materials with rubber flexibility and low friction properties are required to maintain seal performance. By integrating it with PTFE, it can complement the chemical resistance and sliding properties that cannot be satisfied with rubber alone, so it is used as a sealing material such as food and medicine. However, due to the structure, vulcanization adhesion to the rubber material is required, the processing temperature of the silicone rubber is about 150~250℃, and a material that does not change chemically at this temperature is required. However, no material can withstand these temperatures, such as heat resistance, flexibility, and chemical resistance required for packaging. Fluororesin is the only substance with insulation and chemical resistance and a continuous use temperature of 260℃. For the reasons described above, there is no substitute for sealing materials with fluororesin. Even if there are materials that can be applied to individual conditions, the equipment is highly likely to be altered or redesigned, and it is highly likely to be costly. In addition, sealing materials represented by gasket, packing, etc., are often used in various drug solutions and various environments even if they have the same structure and shape. For this reason, the proposed restrictions should be waived. |

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| 8142 | Date:  2023/09/21 10:17  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Belgium  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  We consider that the document attached in this section, as well as the name of the company for which we are submitting these comments, should be treated as confidential (and as such, should not be disclosed), on the basis of two grounds: (i) the protection of the company’s commercial interests, pursuant to Article 4(2), first indent of Regulation (EC) No 1049/2001; and (ii) the protection of legal advice, pursuant to Article 4(2), second indent of Regulation (EC) No 1049/2001. First, the first indent of Article 4(2) of Regulation (EC) No 1049/2001 provides that “[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: commercial interests of a natural or legal person, including intellectual property […] unless there is an overriding public interest in disclosure”. In this respect, it should be noted that Regulation (EC) No 1049/2001 does not define the concept of commercial interests, except in so far as it specifies that such interests may cover the intellectual property of a particular natural or legal person. The EU Courts nevertheless stress that information withheld under the exception relating to the protection of commercial interests is information which is not generally known to persons belonging to the circles dealing with the type of information in question, within the meaning of that provision. The Court held that it is in principle appropriate for an EU institution to rely on general presumptions applying to certain categories of documents, similar general considerations being likely to apply to requests for disclosure of documents of the same nature (Joined Cases C‑39/05 P and C‑52/05 P, Sweden and Turco v Council, EU:C:2008:374, paragraph 50). In this respect, the General Court has for example confirmed that information on company methods and expertise, specific prices, details of budgets and timetables involved, and elements of business strategies were covered by a general presumption that their disclosure would in principle undermine the protection of commercial interests of the company and that the EU institution therefore did not have to put forward any concrete evidence to justify the non-disclosure of each document, in its entirety (Case T-651/21, Hans-Wilhelm Saure v Commission, EU:T:2022:526, paragraphs 106 and 107). In this case, the document attached in this section contains numerous business secrets and proprietary data of the company submitting it, that are not available in the public domain. It contains knowledge about the specific use of a PFAS polymer production aid in the manufacture of a non-PFAS polymer that is used as a food contact material. This expertise and this know-how are not publicly available and their disclosure would cause significant harm to the competitive position of the company, as it would undermine their commercial interests, including intellectual property. Moreover, the document contains and details numerical data as well as R&D work conducted by the company in respect to this particular use. Knowledge of such information could allow third parties such as an applicant for access to document to access such information, that they could possibly use for their own benefit, which could ultimately undermine the commercial interests of the company submitting these comments. Moreover, there is no overriding public interest in the present case that would impose the disclosure of the name of the client. According to the case-law of the EU Courts (see, for example, Case C-127/13, Strack v Commission, EU:C:2014:455, paragraph 128), the burden falls on the applicant for access to documents, first, to demonstrate the existence of a public interest likely to prevail over the reasons justifying the refusal of the documents concerned and, second, to demonstrate precisely in what way disclosure of the documents would contribute to assuring protection of that public interest to the extent that the principle of transparency takes precedence over the protection of the interests which motivated the absence of disclosure (Case T-634/17, Anikó Pint v European Commission, EU:T:2018:662, paragraph 48). As such, it is only where the particular circumstances of the case substantiate a finding that the principle of transparency is especially pressing that that principle can constitute an overriding public interest capable of prevailing over the need for protection of the information (Joined Cases C-514/07 P, C-528/07 P and C-532/07 P, Sweden and Others v API and Commission, EU:C:2010:541, paragraphs 156 to 159). In this case, there is no such overriding public interest nor has one been claimed. Second, the second indent of Article 4(2) of Regulation (EC) No 1049/2001 provides that “[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: […] legal advice […] unless there is an overriding public interest in disclosure”. In respect of that exception, as highlighted by the EU Courts (see, for example, Joined Cases C 39/05 P and C 52/05 P, Sweden and Turco v Council, EU:C:2008:374, paragraph 37), the examination to be undertaken by the institution concerned when it is asked to disclose a document must necessarily be carried out in three stages. First, it must satisfy itself that the document which it is asked to disclose indeed relates to legal advice and, if so, it must decide which parts of it are actually concerned and may, therefore, be covered by that exception. Secondly, it must examine whether disclosure of the parts of the document in question which have been identified as relating to legal advice, would undermine the protection of that advice. Thirdly, if it takes the view that disclosure of a document would undermine the protection of legal advice, it should ascertain whether there is any overriding public interest nevertheless justifying disclosure (See Case C-408/21 P, Council v Pech, EU:C:2023:461, paragraphs 37 to 39). In the present case, we submit that the identity of the client (client-attorney relationships are privileged under ethical rules) as well as the content of the document should be considered confidential under the protection of legal advice. It is, firstly, undisputed that the document constitutes legal advice as it is the work of the clients, with the help of their external lawyers, relating to their engagement by their client to advise them in submitting comments in the context of the public consultation on the PFAS Restriction Proposal. Secondly, the law firm’s identity being linked to the present comments in a public manner, disclosing the name of their client would lead to the disclosure of the privileged and confidential nature of the client’s relation with its attorneys. Thirdly, as demonstrated above concerning the protection of commercial interests, there is no overriding public interest in the present case that would impose the disclosure of the confidential information. The name of the company submitting these comments as well as the document attached in Section V should as such be entirely confidential and their disclosure prevented, in application of the exceptions to disclosure contained in Article 4(2), first and second indents of Regulation (EC) No 1049/2001. | General Comments:  In its current form, the PFAS restriction proposal aims to group and restrict over 10.000 substances, without introducing any differentiation between the different PFAS categories.  PFAS should however be regulated based on a more precise segmentation of the different PFAS categories and only restricting those that present a critical hazard and risk profile for human health and/or the environment.  Article 68(1) of the REACH Regulation requires a demonstration of (i) hazard, (ii) exposure and (iii) availability of alternatives, and the Proposal should reflect instances where either of these criteria are not met.  Articles 68 and 69 of the REACH Regulation relate to the existence of an “unacceptable risk” or “a risk to human health or the environment that is not adequately controlled and needs to be addressed”.  Section 3 of Annex XV relates to information on “hazard and risk” (emphasis added). An Annex XV dossier is used to “initiate the restrictions process” (Article 69(4) of REACH), which is then checked for conformity with Annex XV by the ECHA Committees for Risk Assessment and Socio-economic Analysis (Article 69(4)(3) of REACH). The Annex XV dossier cannot and does not restrict nor limit the risk assessment which the Committee for Risk Assessment (“RAC”) is legally required to carry out in accordance with Article 70 of REACH. The RAC must formulate an opinion “based on its consideration of relevant parts of the dossier” (emphasis added) (Article 70(1) of REACH).  However, the RAC opinion itself must address whether “the suggested restrictions are appropriate in reducing the risk to human health and/or the environment” (Article 70(1) of REACH). It is therefore clear that the RAC opinion is not, and must not, be confined or restricted to the information that the Member State has chosen to include in an Annex XV dossier. The RAC is legally required to carry out a full and valid risk assessment assessing all issues relevant to the appropriateness in reducing the purported risk.  As such, RAC must not: (i) Restrict the assessment to the issues set out in the Annex XV dossier; and (ii) Proceed on an assumption that it was not possible to conduct an assessment of the risk and exposure.  The general presumption that any chemical substance which is a purported persistent substance poses the same hazards and same risks, and that those hazards and risks always preclude and prevent any hazard or risk assessment from being carried out is manifestly wrong in law and demonstrates a clear and manifest misunderstanding and misappreciation of the facts, particularly in the present case.  A core part of an Annex XV dossier is the requirement to provide “Justification for [a] Restriction at community level” (Part 3, Annex XV to REACH) which includes a requirement to determine whether a restriction is the most appropriate Community wide-measure by assessing “(i) effectiveness” and in particular whether: the restriction is: (a) “capable of reducing these risks to an acceptable level within a reasonable period of time” and (b) “proportional to the risk” (emphasis added). It therefore follows that the risk must be quantified.  The raison d'être of the ECHA Committee for Risk Assessment is to assess risk, which it failed to do in this case. Risk is a “function of […] probability” (Case T-13/99, Pfizer Animal Health v Council, EU:T:2002:209, paragraph 147) and relates to the specific hazards and exposures relating to a specific chemical substance. The hazardous properties of all chemical substances differ and are not the same. The whole purpose of a chemical risk assessment is to assess whether a specific chemical in particular, poses a risk – taking into account the properties of the chemical substance itself, and exposure. Merely because a particular chemical substance is, purportedly, persistent does not mean that substance has the same hazardous properties and/or exposure/risk, as other purported or actual persistent substances.  The failure to conduct a risk assessment as required by EU law (there must be consideration of, for example, whether there were any relevant unacceptable risks; what the “critical probability threshold for adverse effects” were; and/or whether that threshold was exceeded in the case of all the products subject to the Proposal), and to use all actual and possible emissions potentially impacted by the proposed restriction as a proxy for unacceptable risk materially impacts the outcome of the assessment. By working from the presumption that any emissions – even potential emissions – potentially in scope of the proposal, should be used as a proxy for risk, means that for those emissions only zero emissions, or no emissions at all, would constitute no “unacceptable risk”. Further, by working from the presumption that (i) any such emissions were a proxy for risk; and (ii) all emissions should be eradicated and minimized, the Commission and ECHA are unable to properly consider the proportionality of the proposal and whether it addressed the activity giving rise to the perceived risk.  The risks arising from exposure and use of alleged persistent substances can be properly and sufficiently controlled. This is clearly accepted and foreseen in the REACH Regulation itself (For example, Article 58(2) of REACH provides that certain uses or categories of uses may be exempt from a REACH Authorisation requirement, provided that, amongst other things “the risk is properly controlled” (emphasis added). Where the risks arising from uses of Annex XIV substances are “properly controlled” it therefore follows that those uses may be exempted from a REACH authorization requirement pursuant to Article 58(2) of REACH. In other words, REACH clearly provides that the risks arising from alleged or actual Annex XIV substances can be controlled and can be properly controlled, such that they have no adverse effects (Article 1(3) of REACH)). Where the risks are properly or sufficiently controlled such they do not adversely affect human health or the environment in accordance with Article 1(3) of REACH and pose no relevant risk, there is no relevant risk and no “unacceptable” risk for the purposes of Article 68(1) of REACH. The notion that it is not possible to characterize or control the risk of an alleged P/M substance is not correct in law or fact.  Neither the Commission nor ECHA have any legal competence to decide that all actual or possible emissions intended to come within the scope of a proposed REACH Restriction automatically constitute “unacceptable risk”. This is particularly the case where there has been no risk assessment assessing or establishing whether such emissions do pose unacceptable risk. By using all actual and possible emissions within the intended scope of a REACH Restriction as a proxy for unacceptable risk, the Commission / ECHA imposes a zero-emissions and zero-risk policy as regards those emissions. |
| Answer to specific info request 6:  Food contact materials and packaging A PFAS use that is missing with regard to food contact materials and packaging is the use of a PFAS polymer production aid in the manufacture of a non-PFAS polymer that is used as a food contact material. This can be achieved by adding a new use (“u”) to point 5 to read “polymer production aid used for the manufacture of a non-PFAS polymer that is used in food contact material applications”. Further specific information on this use is included in the Section V. Confidential Attachment. |

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| 8143 | Date:  2023/09/21 10:18  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | General Comments:  In response to the public consultation on the proposed PFAS regulation (hereafter referred to as the regulation) published by the European Chemicals Agency (ECHA) in March 2023, we hereby submit our opinions as follows: Our company uses fluorinated ethers as part of the refrigerant in our cryogenic heat exchange system. We primarily utilize 3M's Novec7000\*1, Novec7200\*2, and currently considering the usage of China's Noah7000A\*3, Noah7200\*4. These refrigerants are not classified as hazardous substances and are typically used within enclosed space as refrigerant sealed with inert gases. Our system is equipped with safety system which works in various conditions; when there are volume changes due to temperature fluctuations, any pressure drop is automatically supplemented with inert gas, and excess pressure is released by relieving inert gas through a dedicated automatic exhaust line. Additionally, these refrigerants exhibit excellent fluidity and insulation properties at low temperatures, making them widely used in the manufacturing of pharmaceutical raw materials, chemical products, semiconductor materials, and various other applications with no alternative option available at the moment. As it is deemed to be save for environmental and non-toxic according to the test result of Safety Data Sheets (SDS) for these refrigerants, we believe that these refrigerants should not be target of PFAS regulation. Despite the lack of sufficient data to appropriately assess the impact on human health and environment caused by substances subjected to PFAS, current regulation proposal indicates a direction to prohibit the manufacturing, marketing, or use of "PFASs" solely based on their chemical structures. (Currently, regulation proposal evaluates PFAS substances to have "hazardous properties" due to their characteristics of low degradability and high persistence, but lacks empirical evidence of the harm to human health or the environment). We believe that instead of a full ban on the production, marketing, or use of all "PFASs," a more sensible approach should be applied; assessing the risks based on scientific evidence for each individual substance and banning only substances that clearly harm human health and the environment. We further believe this sensible approach should be applied as REACH regulation proposal also stipulates that restriction(s) or amendment(s) might be made if there are unacceptable risks to human health or the environment arising from the manufacturing, marketing, or use of substances. (We especially believe that substances with high molecular weights, such as fluoropolymers, should not be subject to regulation as these substances practically insoluble in water so it is hard to be absorbed into human body and have no confirmed harmful effects even in pure liquid form) A full prohibition on the production, marketing, or use of "PFASs" will affect economic and society significantly. Eliminating "PFASs" from the market in a situation where alternative substances are difficult to come by could disrupt global supply chain and international trade of products containing PFAS. Additionally, this regulation will add additional burdens for the identification and development of alternative substances to various companies within unreal and short time. Considering these uncertainties and additional burdens, it is not wise to adopt a regulatory approach that apply full ban over a thousand different "PFASs." As mentioned above, we believe it is crucial that the scope of regulation is limited to substances that have been assessed for their impact on human health or the environment based on scientific evidence, taking into consideration the economic and societal implications. Moreover, the selection of substances subject to regulation should be made carefully, considering a wide range of knowledge, including opinions from public consultations, and assessing the availability of alternatives. Additionally, necessary measures should be taken to allow for the exclusion of substances from regulation or extensions of grace periods if it becomes clear after the implementation of the system that there are significant impacts on the economy or society, or if the development and social implementation of alternative substances cannot be sufficiently anticipated during the transition period. \*1) CAS Number: 375-03-1 \*2) Mixture of CAS Numbers: 163702-06-5 and 163702-05-4 \*3) CAS Number: 382-34-3 \*4) CAS Number: 163702-06-5 |
| Answer to specific info request 1:  Applications of fluorinated gases, refrigerant |

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| 8144 | Date:  2023/09/21 10:19  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Belgium  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The document contains confidential business-critical information, which might influence stock prices. | General Comments:  See attachment. |
| Answer to specific info request 6:  a. Fluoropolymer waste from end-of-life machines and service parts: The fluoropolymer waste we generate today 2023 in the EU, coming from end-of-life machines and service parts, is estimated at < 5 ton yearly. - Our machines and spare parts contain > 90% recyclable metal. At end-of-life, the majority of our machines and spare parts are sent to metal recyclers, and PFAS that is attached to these metal parts (coatings, seals,…) are hence burnt at > 1300 degrees, meaning that all PFAS is destroyed. - Certain small PFAS containing parts, such as O-rings, that are replaced during a service, are gathered in industrial waste, and are hence burnt as well at high temperatures (> 850 degrees). Although at these temperatures, PFAS could still be present in rest fractions, but the PFAS weight in these O-rings is marginal versus the total PFAS weight in machines and spare parts. Fluoropolymer waste gathered in our production: The production waste amount is marginal as compared to the waste from end-of-life machines and parts. PFAS waste generated in our shops (from coating etc.) is gathered as chemical waste, and burnt at > 1000 degrees, so all PFAS is destroyed. After our waste handling, only a marginal PFAS fraction is left. Fluoropolymer emissions during in-use: No emissions are expected. b. The main functionality of fluoropolymers in our parts is to make compressors leak tight (guarantee safety and performance) and resistant against very low and high temperatures (-260 up to 425°C), high pressures (0-1000 bar), aggressive gas/liquid mixtures (air, oxygen, oil, chloric, acids, glycols, condensate,…), and reduce the friction (to reduce wear, increase lifetime, and to increase performance) under those conditions. Fluoropolymers, such as PTFE, FEP, FKM, viton,… are used in compressor elements, filters, dryers, motors, bearings, valves, electrical components, hoses,… as coatings, seals, O-rings, insulating material, anti-bacterial, hydro/oleophobic material,… The key functionalities of fluoropolymers are required in these parts, we only use PFAS where absolutely necessary, see examples of flow charts and drawings in our attached position paper (confidential). d. Compressed air is known as the “fourth utility”, apart from electricity, gas, and water. This is not well known, because compression mainly occurs in an industrial environment. 10% of the electricity consumption in industry is related to compression. A compressed air net is required in almost any manufacturing facility, among which in essential sectors such as medical, pharma, food/beverage,... Compressing air/gas is intrinsically coupled to heating and pressure build-up. Compression also needs fast-moving parts, and happens in aggressive environments (gas and liquids). It is the unique combination of properties that makes fluoropolymers indispensable in compression. We only use fluoropolymers on parts where it is absolutely necessary for performance, safety, reliability. Replacing PFAS by currently available alternatives (PEEK, HNBR, EPDM,…) will lead to shorter lifetime, more failures, more service (parts), lower performance, leaks,… because these alternatives do not have the combination of properties PFAS have. See position paper for an example (confidential). - More failures and shorter lifetime lead to more spare parts needed, and hence more waste in total. Moreover, more service intervals lead to more transportation and a higher GHG footprint. - Lower machine performance leads to more energy-usage for the same output (air pressure) and hence a higher GHG footprint. - Air/gas leaks not only lead to a lower performance, but also cause unsafe situations (explosion & health risks). As almost all of our machines contain PFAS (as well as competitor machines), we expect major shortages on the market for these (inferior) PFAS-free alternatives. Moreover, the stricter legislation in Europe creates an uneven level playing field for companies with customers worldwide. e. We rely on suppliers for alternatives. Our suppliers have informed us that alternatives with similar properties are not available/developed yet (“essential”) or even not possible at all (“critical”) within the current scientific knowledge state, due to the unique combination of properties which is indispensable in compressing air/gas. In those “essential” uses, we require multiple years (6.5-13.5) for: - Development (new formulation, new chemistries,…) - Redesign (making sure that running conditions are less harsh) - Testing - Implementation R&D costs for new product development in case alternatives are possible but not developed yet (“essential”): ~5.000.000 euro/product type (for +/- 150 types) For “critical” uses, we require time-unlimited exemptions. Spare parts are designed for a particular machine setup. PFAS-free spare parts need to be designed in such a way that they at least fit 100% geometrically and moreover keep the original functionality/performance of the part. Doing this for an immense installed base is impossible (research, design, validation, sourcing & production, logistics). Existing machines will hence become inferior, irrelevant and/or stop working in the applications of our customers. We, therefore, ask for specific exemptions for spare parts for already installed products in the field. See position paper for a detailed overview of uses and requested exemptions (confidential). Discarded alternatives have lower performance, higher energy-consumption (higher GHG emissions), more and sooner failures, leaks,… Examples are mentioned in the position paper (confidential). f. If alternative chemistries are possible and would be available right now, then it would take us in any case more than 18 months (as is currently proposed) i.e. 36 months to phase-in, due to: - Lead times (an order placed today often takes over 18 months to be manufactured and delivered) - Administration (converting drawings, manuals,…) - Testing (a typical redesign project takes more than 18 months) - A massive number of parts affected (PFAS is present throughout our portfolio, which means 1000’s of affected part numbers) Product development cost: If alternatives would be available: 500.000 euro/product type (for a few hundred types) Operational cost: Lower performance leads to higher energy consumption and hence higher energy cost. The best candidate technology to be made PFAS free currently uses 20% extra energy, hence a 20% higher GHG emission. Moreover, if a customer requires an air delivery which cannot be met with the current machine anymore, he must buy an oversized machine. More failures and shorter lifetimes lead to more service and more spare parts. g. Fluoropolymers are used in most of our equipment. Only for machines that operate in mild conditions, we would be able to phase-out PFAS over time (however, 18 months is not possible, see section f above). This is true for about 30% of our product portfolio. If the proposal is accepted (taking into account the time extension of the standard phase-out period, i.e. 36 months), we expect a business revenue loss of 70% and employee loss of 70%. (Remark: the effect for us is worldwide, because in our chemical strategy, we dedicate to follow worldwide the most stringent legislation for all our products, also for products manufactured and sold outside of EU.) This is only the direct impact for our company. But as we deliver compressed air installations to enable production in other companies, complete industries will be impacted by the lack of compressed air. In other words, the indirect effect of a lack of our equipment will be huge. |

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| 8145 | Date:  2023/09/21 10:20  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |

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| 8146 | Date:  2023/09/21 10:25  Content:  Scope or restriction option analysis  Hazard or exposure  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment: | General Comments:  Please see our STATEMENT TO GENERAL BAN ON PFAS-MATERIALS IN EU uploaded. |
| Answer to specific info request 1:  In STATEMENT TO GENERAL BAN ON PFAS-MATERIALS IN EU refers to the abilities of PFAS on sealing and guiding |

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| 8147 | Date:  2023/09/21 10:26  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  EWM GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  please see attached file |

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| 8148 | Date:  2023/09/21 10:33  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sang-A Frontec  Org. country:  Korea, Republic of | General Comments:  SANG-A FRONTEC CO.,LTD is a company that specializes in processing fluoropolymers in Korea We request that fluoropolymer such as PTFE and PFA parts in OA (Printer, Copier) be completely excluded from ECHA's PFAS restrictions.  Fluoropolymer is the only material that has heat resistance, wind resistance, chemical resistance, water resistance, lubricity, and unique optical/electrical properties at the same time. And it has been used as an essential material in many fields, including the chemical industry, medical field, new energy field, telecommunications field, semiconductor field, transportation field, and environmental field. Although there are materials that have one of the characteristics of fluoropolymers, there is no single material that has all of the great properties at the same time. Fluoropolymers are expensive and are chosen when other materials cannot meet the requirements. In certain situations, alternative materials are already being used for cost considerations when other alternatives are available. Fluoropolymers are chosen only when other materials cannot be substituted. Therefore, there is no substitute for the specific properties and combinations provided by fluoropolymers in these applications.  At the end of its service life, fluoropolymers can completely decompose into hydrogen fluoride at high temperatures above 800℃. According to a study by Krasimir Aleksandrov et al., no 31 PFAS substances were found during municipal incineration of PTFE using BAT. This shows that high-temperature incineration of fluoropolymers is an acceptable and safe form of waste disposal. (Attachment 3, Krasimir Aleksandrov et al., “Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas,” Chemosphere 226 (2019) 898-906) In 2022, global annual consumption of fluoropolymers is expected to be approximately 500,000 tons, and the industry itself is expected to generate revenues of 10 billion euros. Although the fluoropolymer content in the end product is very low, they provide the end product with a specific, irreplaceable combination of performance, creating social and economic value that far exceeds the impact of the industry itself. In general, some of the alternative materials may have similar properties to fluoropolymers in terms of parameters or performance, but the combination of properties required for the application is what distinguishes fluoropolymers from other alternative materials. The impacts of switching to alternatives include reduced performance, reduced durability and reliability, and increased weight, and certain applications, such as semiconductor manufacturing, can be severely affected. Economic impacts include setbacks in advanced technology, loss of efficiency, and higher capital and maintenance costs. The diversity of fluoropolymer applications means that material changes can have significant design implications as well as product quality issues. Environmental/health and safety impacts include reduced operating safety of the equipment and increased risk of releasing hazardous substances into the environment. Therefore, SANG-A FRONTEC insists that fluoropolymers be excluded from the scope of the proposal. |
| Answer to specific info request 6:  OA (Printer, Copier) PTFE or PFA parts are essentially used as Rollers, claws, separator etc because PTFE, PFA have low friction and resistance to heat. |

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| 8149 | Date:  2023/09/21 10:36  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  KITAMURA LIMITED  Org. country:  Japan  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  ＜Table 9 already listed＞ No Listed ＜Sectors and (sub)use that are not listed in the restricted proposal and wish to be added＞ Printing inks ,especially for used for notations related to the safety and life of users, such as names of raw materials and handling instructions. |

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| 8150 | Date:  2023/09/21 10:41  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sang-A Frontec  Org. country:  Korea, Republic of | General Comments:  SANG-A FRONTEC CO.,LTD is a company that specializes in processing fluoropolymers in Korea We request that fluoropolymer Film, Sheet, etc. be completely excluded from ECHA's PFAS restrictions.  Fluoropolymers play an important role in virtually all industries. Within the industry alone, the uses would run into hundreds of thousands of applications, each one reliant on the unique combinations of properties found with fluoropolymers (both fluoroelastomers and fluoroplastics such as PTFE): • Chemical resistance • Thermal resistance • Mechanical properties • Low permeability • Low leachable and extractable content • Low surface energy • Low flammability (cannot sustain a flame) • Low friction • High levels of cleanliness (impurities measured in parts-per-trillion in some cases)  The strength of the carbon-fluorine bond and the polymeric structures of these polymers is unsurpassed. In the years since their developments in the 1950s, there has been no success in finding alternative materials which can serve to replace or improve on their performance – a period of almost 70 years. There are no technical alternatives available to fluoropolymers in all applications. This is not for the want of trying. It is also not related to cost/benefit drivers. For example, perfluoroelastomers (FFKMs) have a market price more than Eu1000/kg, with some varieties costing three times that. These polymers are used as a last resort where other products and/or designs cannot be used.  With 70 years already passed since the commercialization of fluoropolymers, the chances of discovering and commercializing new alternatives within a timespan of proposed derogations (up to 13 years) is extremely unlikely if not impossible.  The derogations are contradictory - they immediately ban the monomers but leave derogations for the polymers. So even though fluoropolymers could be used in areas covered by derogations, the restrictions on the monomers prevents the polymers being produced or imported. |
| Answer to specific info request 6:  We produce Sheets and Films for the applications as below, and PFAS should not be restricted because there are no replaceable substances. 1. Insulation and sealing for condensor PTFE SHEET is used inside the cap to prevent leakage of the condenser electrolyte. Basically, it has flame retardancy, inertness, and low friction. Fluoropolymer is the only material that has insulation and chemical resistance and a continuous use temperature of 260℃. 2. Release film for hot press process When pressing multiple layers of films and plates on a PCB substrate with heat, PTFE SHEET is used to prevent the top and bottom layers from sticking to the mold. 3. Release film for display bonding This is also used as a release film when pressing multi-layer films and plates with heat. It has heat and release properties, so it makes the most reasonable. |

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| 8151 | Date:  2023/09/21 10:40  Content:  Scope or restriction option analysis  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  Because it contains our confidential evaluation data. | General Comments:  Our company supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV. Please see Section V for information on alternatives we offer. |
| Answer to specific info request 1:  Elecrtronics and semiconductors [Semiconductor manufacturing process] Please check Section V Attachment. |
| Answer to specific info request 6:  Please check Section V Attachment. |

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| 8152 | Date:  2023/09/21 10:39  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |

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| 8153 | Date:  2023/09/21 10:42  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Taiwan  Company name confidential:  Yes | General Comments:  An undifferentiated PFAS ban would have serious negative economic consequences. There are no alternatives to FKM, FEPM, FVMQ, PTFE and especially to FFKM sealing materials.It is desirable to be recognized as an 'exempt substance' . |

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| 8154 | Date:  2023/09/21 10:43  Content:  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  KUKA Deutschland GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  The attached information contains sections of data sheets from third parties. Although these are in the public domain, distribution may not be desired. | General Comments:  Request for exemption: Machinery and equipment manufacturing industry is missing as a sector in the restriction proposal. We are producing industrial robots for the automobile as well as the general industry and requesting following exemptions: PTFE & FKM for sealings in industrial machinery and equipment. PTFE & FKM for cable sheathing in industrial machinery and equipment. PTFE & FKM for electronics in industrial machinery and equipment. As we are subject to a 30-year spare parts obligation and no alternative is currently known for the parts concerned, we request an unlimited exemption for the above-mentioned substances and applications. This requirement is justified because the PFAS-polymers are used in industrial and not in consumer products. |
| Answer to specific info request 2:  During the manufacturing phase of our products, we closely monitor and address any potential issues to ensure the highest quality standards. Through rigorous quality control measures we aim to minimize rejects of seals, cable sheaths, and the potential risk of lubricant loss with PFAS included. An emission into the environment is very unlikely. During the use phase, our industrial robots are used within a closed environment, ensuring a controlled and safe operational setting. An emission into the environment or exposure to workers are very unlikely. Our industrial robots are stationary large scale industrial machines with no mobility during their use phase. Additionally, a study from Stephen H. Korzeniowski et al. - 2022 has presented data demonstrating that the fluoropolymers meet the widely accepted criteria for polymer hazard assessment to be classified as a PLC. The data presented indicate that the fluoropolymers studied exhibit thermal, biological, and chemical stability, are minimally soluble in water, have low mobility, limited bioavailability, no bioaccumulation potential, and are non-toxic, with low levels of impurities. These findings further underscore the need to treat the fluoropolymer class as a distinct entity and not to categorize it with other PFAS for the purpose of hazard assessment or regulatory considerations. A statement in the EoL question is not feasible. Most of our customers scrap our products themselves. We are currently carrying out a PFAS inventory but cannot make any precise statements before this is completed. |
| Answer to specific info request 6:  A) We don't have information on this topic B) The Use Sector involves the assembly of Industrial robots, which is not explicitly listed in Annex XV. Generally industrial machinery and the production process are not considered and should be added as a use sector. We agree with the demands of the VDMA in their position paper. (attachment 1) In our manufacturing process, we incorporate a range of essential components such as seals, lubricants, electronics and cable sheathing. These components play a crucial role in ensuring the performance, durability, and safety of our industrial robots. Our suppliers are held to strict standards, ensuring that the materials exhibit specific properties such as friction resistance, heat resistance, wear resistance, and resistance to various media. Some of our industrial robots act under harsh environmental conditions, e.g., foundries, clean rooms, or hygienic environments. Some of our industrial robots are optimized for the extreme conditions in washing cells. These industrial robots need the high protection class IP69 suited for wet chemical cleaning, immersion, and high-pressure cleaning processes - even in combination with highly active cleaning agents and disinfectants. To assure a product usable under these conditions, sealings are used which can withstand such mediums and can handle high rotational speed and resulting friction at the same time. Evidence can be found in the attachment 2 & 3. Right now, we have no alternative except PTFE and FKM. These sealing prevent leakage of oil, which is important in the industrial food industry. For the robotic industry special cables are manufactured to withstand the 3-dimenisonal movement and the Influences of e.g., cleaning agents. For the winding and isolation outside of these cables PTFE is, under harsh conditions, the only alternative. C) We don't have information on this topic D) At present, we do not have information on any technically and economically feasible alternatives for the components in question. However, we maintain an ongoing and active dialogue with our suppliers, exploring the possibility of identifying alternative materials that can meet the same rigorous standards for safety and functionality as the current components. Our commitment to providing durable and high-performance industrial robots remains unwavering, and we are diligently investigating the availability of alternatives for seals, lubricants, and cable sheathing that do not contain PFAS. While we are open to exploring new possibilities, it is important to note that, as of now, we have not found substitutes that fulfill the required criteria for safety and durability without incorporating PFAS. One possible alternative proposed in Annex E for PTFE in sealings is NBR. However, as shown in our attachment 2 & 3, NBR does not meet the criteria for some applications our industrial robots are built for. Under harsh conditions PTFE currently is the only material which can withstand such conditions and last for a reasonable long use phase. E) Given that our search for alternatives and discussions with suppliers are still in their early stages, it is challenging to determine the exact timeframe and potential financial implications of finding substitutes for all the components. As we prioritize providing safe, durable, and high-quality industrial robots, we propose seeking for industrial machinery a PTFE / FKM derogation for seals, cable sheathing, and electronics an unlimited exemption. We will continue our efforts to explore viable and sustainable alternatives that meet the required safety and performance standards. The derogation will provide us with the necessary flexibility to conduct thorough research, conduct testing, and make informed decisions without compromising on the quality and functionality of our industrial robots. Leakage, which could be caused by seals with inadequate requirements, would cause oil or grease to escape from the robot into the environment. F) See point E) G) The durability and functionality of industrial robots could potentially be compromised to a lower level if we are unable to find suitable substitutes for PFAS-containing components. It is important to recognize that robotics is a significant global megatrend, and if competitors outside the EU can offer industrial robots without PFAS restrictions, they may gain a competitive advantage and expand their market share. This situation poses a considerable challenge to the European robotics industry, as it could lead to a disadvantage in the global market and hinder its growth and innovation potential. Moreover, it may adversely impact Europe's overall future viability as a technology leader. |
| Answer to specific info request 7:  We are not aware of any alternatives to PFASs in the electronics industry. According to our electronics suppliers, there is also no comprehensive overview of which products and processes might contain PFAS. This poses a significant challenge for our company, as the use of PFASs could be widespread in numerous electronic applications. The socio-economic impact for our company could be catastrophic, as a possible supply shortage or even a production shutdown would accompany a PFAS restriction. Additionally, we are subject to a 30-year spare parts obligation. We therefore propose an unlimited exemption for PTFE and FKM in electronic components in industrial machinery. |
| Answer to specific info request 8:  We talked in a personal dialogue with multiple people from our main electronic supplier. They not only have no overview about PFAS used in components, nor are they capable of providing substitutions or alternatives in the next years. It is impossible to identify PFAS in the electronic components bought on the market. We, as a downstream user, strongly suggest an unlimited derogation, otherwise the electronic industry can not handle the shift to a more transparent policy. Otherwise, it is impossible to fulfill a full material declaration, needed for compliance with a regulation of this extensive scope. |

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| 8155 | Date:  2023/09/21 10:47  Content:  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United Kingdom  Company name confidential:  Yes | General Comments:  Raman spectrometers are used for detailed chemical and structural characterisation for use in varied and far-reaching fields of technology and research. With the manufacture and use of spectrometers and their accessories, careful consideration must be made with the selection of materials to ensure no contamination of results from analysis is possible due to the manufacture of the equipment, and therefore results from such work having a high level of integrity. This includes subcomponents used with the manufacturing process, especially O rings, seals, adhesives and lubricants, finishes, fibre optics plus bespoke optical components which are otherwise unavailable on the market. All must be resistant to a wide range of chemicals and environments, including high vacuum environments. The stable properties of FKM and similar long chain PFAS are specifically necessary to support the fundamental purpose of the equipment to these applications. Repeated evaluation of alternative materials has shown that the overall performance of PFAS is unmatched. Based on work carried out while selecting and qualifying materials, alternatives result in reduced reliability (an increased safety hazard) and shorter product lifetimes (resulting in higher levels of environmental waste). Raman spectrometers are not adequately covered in section E.2.4 of the Proposal for Restriction and should be considered separately due to their broad impact on key and wide-ranging research fields and industry, requiring the need for detailed and highly specific structural and chemical characterisation, plus their long lifetime being used for such work. We recommend that consideration is given to the risk vs benefit of the use of larger fluoropolymers and that the ban targets high polluters and substances likely to cause environmental harm first, phasing in control of less harmful PFAS over a realistic timeframe. The timeframe for finding and qualifying alternative materials is very short. |
| Answer to specific info request 1:  The industry and research sectors that use our Raman analytical products are wide ranging and include (but not limited to) healthcare support (research, diagnostics and medicines), renewable energy generation and storage (solar cells, novel battery technology, energy storage and delivery materials), research into materials with novel properties (2D materials such as graphene), biological, forensic science, art and historical artefact conservation, semi-conductor manufacture, particle and liquid analysis, microplastics (the identification and monitoring of microplastics within ecosystems and manufacturing processes) plus manufacturers of all products where materials science is required to determine the composition, distribution and understanding of materials in a wide range of applications. In all these cases it is also important that our products do not leak or leach contaminants that will affect the results of such work and subsequent conclusions, including critical processes for manufacture (such as Li+ battery production) or damage of sensitive or rare samples (such as works of art). The resistant, passive nature of FKM and similar PFAS provide this. |
| Answer to specific info request 2:  a) Usage phase: The service life of products typically exceeds 20 years and is supported by repair and upgrade packages. There are only low levels of emissions during the usage phase, typically through loss of PFAS contained in certain lubricants. b) End of life: PFAS only form a small percentage by weight of the product, the main constituents are metals, mainly steel. Our products are recycled as scrap metals (Electronical and Electricals are managed under WEEE). PFAS are not separated from metal parts and processed at high temperatures along with the metals. Processing temperatures exceed the temperature at which PFAS will be destroyed. |
| Answer to specific info request 3:  Recycling does not result in PFAS release or formation. |
| Answer to specific info request 4:  Due to the relatively low volume of PFAS and the long active life of this product type there are no significant impacts on the recycling industry. Our suggestion is that consideration is given to collection and recycling of items that include PFAS. Control of collection and recycling can be implemented easily in B to B environments. Regulations could be implemented through parallel legislation such as the Waste Framework Directive. |
| Answer to specific info request 5:  The total annual consumption of PFAS is unknown. Calculations show that an annual mass of O rings and seals used within Raman spectrometers amounts to 2,5kg maximum (combined weight of all physical O rings and seals) with negligible amounts of PFAS within other materials used in the production of Raman spectrometers. Limited amounts of PFAS emissions in manufacturing – industrial cleaners (derogation). Aside from recycling at end of life, there is negligible release of PFAS. |
| Answer to specific info request 6:  Key functionalities provided by PFAS are based on the unique properties of PFAS materials including their stability in hostile environments, resilience, and low friction. To the best of our knowledge and from the results of our own testing and evaluation, indications show that suitable alternatives are not yet available. For certain niche applications substitution is not technically or economically feasible. Use of PFAS in analytical equipment (Raman spectrometers) is important to ensure there is no possibility of contamination from the materials used within the manufacture and use of the equipment (O rings, seals, adhesives and lubricants, finishes, fibre optics plus bespoke optical components which are otherwise unavailable on the market) to ensure spectral results originate from the materials of interest only, and results have high integrity. |
| Answer to specific info request 8:  Alternative materials are being sought and further work is being done work to evaluate alternatives where they are found. To date no materials adequately meet the mechanical, thermal, and chemical stability offered by PFAS solutions. |
| Answer to specific info request 9:  No information to add on the degradation pathways. |

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| 8156 | Date:  2023/09/21 10:48  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 1:  - Professional apparel (including PPE) - Technical textiles We are producing CBRN protective suits which are mainly worn by armed forces and law enforcement, as well as by civil first responders. |
| Answer to specific info request 2:  We need PFAS finishes to create water and oil repellent characteristics on the outer shell materials of our CBRN protective suits which in turn creates repellency to liquid chemical warfare agents. We purchase the FC-treated outer shells and combine them with our filter material. According to our analysis and calculation, the maximum PFAS content is approximately 0,3 g per suit. The disposal of the suits is the responsibility of the users. As far as we know the majority of the PPE will remain in the inventories and should be disposed of in the unused state in its original packaging by controlled incineration. The PFAS effectively released to the environment is expected be only a fraction of the total PFAS content of the products. |
| Answer to specific info request 5:  Please see paragraph 2. We have no information about potential PFAS emissions during the upstream proccesses. |
| Answer to specific info request 6:  b.) The PFAS finish enables the liquid chemical warfare agents to roll off the material or to remain on the surface without sinking into the material in the liquid form. Vice versa, without the repellency these substances are able to sink into the material and thus can reach the skin of the wearer which leads to life-threatening injuries. Chemical warfare agents have a suffocating, paralyzing or toxic effect and can damage the skin, lungs, nerves or blood. Even contact with very small amounts of these substances can kill or seriously injure humans. c.) While we cannot answer for the whole sector, we can answer this for our own supply chain. - Directly effected by PFAS limitation: low single digit number (outershell manufacturers) - Impact on our business does have an indirect effect on our supply chain: low two digit number (further components and services) d.) To our knowledge there is no other chemical formulation or method that can be used as an alternative to PFAS finish to provide sufficient repellency to liquid chemical warfare agents. e.) To date, we are not aware of any research approach that indicates the development of a suitable product for the repellency of liquid chemical warfare agents. The suitability of potential alternatives would have to be evaluated in elaborate application-specific procedures with real live chemical warfare agents. The research of possible alternatives is ongoing. However, we assume that no qualified alternative solution will be available in the foreseeable future. Due to the uncertainty about development approaches and their suitability we cannot offer answers for subitem f. g.) The biggest impact by the unavailability of suitable or safe PPE is on the users (military, first responder, law enforcement) who will not be protected in operations in CBRN environments. |
| Answer to specific info request 7:  In the current restriction report, an exception applies to textiles used in personal protective equipment after the PPE regulation 2016/425 to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m). Defence personnel and law enforcement are not governed by the PPE regulation but can be exposed to the same risks as listed in Risk Category III. We therefore request to extend the exemption for PPE by including PPE for law enforcement and armed forces: Concerning CBRN hazards, which present a threat to law enforcement and armed forces, we would like to refer to an entry in the Annex E to Annex XV Restriction Report, page 26 where two national defence ministries point out the need of PFAS for PPE for military activities. For all of these user groups: The disposal of the suits is the responsibility of the users. As far as we know the majority of the PPE will remain in the inventories and should be disposed of in the unused state in its original packaging by controlled incineration. The PFAS effectively released to the environment is expected be only a fraction of the total PFAS content of the products. |

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| 8157 | Date:  2023/09/21 10:49  Content:  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  Individual  Country:  France  Attachment: | General Comments:  EWA-European Welding Association The European Welding Association (EWA) is an industrial association which comprises national associations and manufacturers of arc welding and cutting equipment, welding consumables, flame welding and cutting equipment and allied processes and health and safety equipment for welders from across Europe. EWA is registered to the the EU Trasparency Register (id number 711840531940-21) In particular in the scope of application of the Flame Equipment are covered all technologies in different oxy fuel sectors. The PFAS restriction as defined in the restriction proposal will have strong impact in all sectors where Flame equipment is used - potentially in every workshop where metal is cut and welded or brazed as all the following products contain PFAS: -Valves included cylinder valves -Pressure regulators -Flow Regulators -Gas distribution systems -Welding and cutting and heating blowpipes -Low pressure safety devices -Hoses (low pressure and high pressure)  In our sector PFAS, mainly FLUOROPOLYMERS, are used typically as sealing solutions (eg. Gaskets; O rings ; seats) and are used as for their properties to obtain: -resistance to high temperature -resistance to aggressive chemicals -low friction -Impact resistance -long term stability For what in our knowledge and as reported us by our member Companies and to them to their suppliers, the PFAS used in Flame equipment would be at the moment irreplaceable. We also underline that always is important to consider that all the PFAS used in our products are essential to maintain safety in order to avoid leaks of oxygen and flammable gases with the risk of fire and explosion. For what in our knowledge, we understand that FLUOROPOLYMERS are usually considered chemically inert, not soluble and non bio-accumulative. They wouldn't have the environmental and toxicological profiles associated with any other PFAS that are of concern. For all these reasons as in our sector the PFAS used are mainly FLUOROPOLYMERS, we sustain: the request of a TOTAL EXEMPTION for FLUOROPOLYMERS (Subordinately for fluoropolymers), to request EXTENDING THE SCOPE OF THE 13,5 YEARS DEROGATIONS for all Per- and polyfluoroalkyl substances (PFAS) to: NEW Use: COMPRESSED, LIQUEFIED AND DISSOLVED GAS APPLICATIONS NEW sub use: -equipment for gas production -receptacles gas filling -gas transportation according to: TPED 2010/ 35/EU Regulation ADR (The Agreement concerning the International Carriage of Dangerous Goods by Road) -gas uses handling, distribution in buildings, pressure reduction, dosage of gases and flame control for cutting, welding, brazing, soldering and allied processes in industrial, professional and not professional applications. |
| Answer to specific info request 6:  NEW Use: COMPRESSED, LIQUEFIED AND DISSOLVED GAS APPLICATIONS NEW sub use: -equipment for gas production -receptacles gas filling -gas transportation according to: TPED 2010/ 35/EU Regulation ADR (The Agreement concerning the International Carriage of Dangerous Goods by Road) -gas uses handling, distribution in buildings, pressure reduction, dosage of gases and flame control for cutting, welding, brazing, soldering and allied processes in industrial, professional and not professional applications.   a. no information b. -resistance to high temperature -resistance to aggressive chemicals -low friction -Impact resistance -long term stability c. The number of companies in the sector estimated to be affected by the restriction. A) EU estimated manufacturers of Flame Equipment Estimated 50-60 manufacturers B The number of companies that will be affected by the restriction is not countable as the Flame Equipment products are daily used in each place where metal is cut welded, brazed, heated d. no information , refer to the comments submitted by manufacturers e. no information , refer to the comments submitted by manufacturers f. no information , refer to the comments submitted by manufacturers g. no information , refer to the comments submitted by manufacturers information on what the socio-economic impacts for sub use  105 Million €/y turnover for flame equipment (total in EU + Turkey), source EWA https://european-welding.org/communication/ewa-presentation-and-characteristics-of-the-european-market/  thousands of employees / professional welders (total in EU, direct and indirect) The number of employees / professional welders that will be affected by the restriction is not countable as the Flame Equipment products are daily used in each place where metal is cut welded, brazed, heated  thousands of consumers / hobby welders (total in EU) The number of consumers / hobby welders that will be affected by the restriction is not countable as the Flame Equipment products are daily used in each place where metal is cut welded, brazed, heated |

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| 8158 | Date:  2023/09/21 10:51  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sang-A Frontec  Org. country:  Korea, Republic of | General Comments:  SANG-A FRONTEC CO.,LTD is a company that specializes in processing fluoropolymers in Korea We request that fluoropolymer tubes, hoses, etc. be completely excluded from ECHA's PFAS restrictions.  We support the views reported with regard to the proposed restrictions issued by the Conference of Fluoro-Chemical Product Japan (FCJ) and the Japan Fluoropolymers Industry Association (JFIA).  Fluoropolymers are extremely useful materials that various outstanding properties such as high heat and chemical resistance, outstanding electrical properties, and non-adhesion. This puts them in high demand by the automotive, electronics, chemical, medical, and aerospace industries, and contributes to the development of each industry by imparting their unique performance and properties. Whereas fluoropolymers possess the various features as mentioned above, the proposed alternatives are inferior to them in both functionality and performance.  Polyfluoroalkyl substances) proposed by 5 European countries is an excessive measure because it restricts more than 10,000 of organofluorine compounds (PFAS) on the grouping basis that they are persistent as substances of concern equivalent to the already regulated PFOS and PFOA. The environmental and toxicological profiles are distinctly different in Fluoropolymers solids than the majority of other PFAS liquid chemicals. The assumption that chemical properties are transferred to every instance of occurrence is unfounded and as such the restriction is invalid.  Annex 68 of the Proposed Reach Restriction requires that Fluoropolymers which “pose risk to human health or the environment that is not adequately controlled and needs to be addressed”. Fluoropolymers are inert and do not cause harm to humans or the environment. Fluoropolymers are used for medical applications where devices are inserted and remain in the human body. These have been in use for over 60 years which his proof of their lack of harm and toxicity to humans.  Fluoropolymers do not break down to form harmful chemicals, as has been proven by the Danish EPA. They have been classified as polymers of low concern as documented in the Society of Environmental Toxicology and Chemistry by BJ Henry published 9th February 2018. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035  Fluoropolymers meet the OECD Polymer of Low Concern (PLC) criteria. They are non-toxic, not bio available, non-water soluble and non-mobile molecules and are deemed as such to have no significant environmental and human health impact. https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm |
| Answer to specific info request 1:  We produce Tubes and Hose for the applications as below, and PFAS should not be restricted because there are no replaceable substances. 1. Semiconductor process and facility It is used in piping when transporting fluids, gas detectors, and heat exchangers, and the only material with various physical properties such as chemical resistance, lubrication, and heat resistance is fluoroplymer. 2. Printer and Copier Toner-fusing films made to be equipped in laser printers and copiers It is used for release from toner in the fusing roller and withstands the high temperature coming from the heater. 3. Cable cover Some special specifications wires use fluoropolymer based covering tube. It is heat-resistant and flame-retardant, has high insulation strength and is cost-effective. |
| Answer to specific info request 6:  For the manufacturing of Toner-fusing films/belts, we use polytetrafluoroethylene (PTFE) and perfluoroalkoxyalkane (PFA), both of which belong to fluoropolymer family. Approximately 3 metric tons of PTFE/PFA contained in the toner-fusing films/belts are sold in the EU market annually. Fluoropolymer has been the only material with all the properties required for our toner-fusing products: high-heat resistance, releasability, and oil-repellency. A toner-fusing films/belts containing fluoropolymer can fuse toner firmly onto a sheet of paper by using heat and pressure. During the process, it must release all the toner without leaving any trace. No other know materials could do the same as fluoropolymer does. If the use of fluoropolymer-coated toner-fusing films/belts are outlawed, approximately 500,000 employees of over 5,000 businesses, including office equipment manufacturers, material/parts suppliers, and retailers/distributors, will be affected within the EU countries. For the photocopiers and printers with Carlson-process electrophotography, the toner needs to be fused firmly onto a sheet of paper by heat and pressure. Simultaneously the fusing device (either a film or a belt) needs to release all the toner on its fusing surface. This process requires high toner-releasability, high-heat resistance, and wear-resistance of the fusing device. Presently, fluoropolymer is the only material of choice for the toner-fusing device. The reason that fluoropolymer is the only choice and there is no alternative is its high toner-releasability. Low releasability of the fusing surface will result in toner residues, which will cause defective printings. There are many materials with high-heat resistance and wear-resistance properties. Among them, fluoropolymer and silicone polymer are known to have high releasability. The indicators of releasability are contact angles with water, and contact angles with hexadecane. The contact angles of fluoropolymer with water and hexadecane are 114 degrees and 45 degrees respectively, while the contact angles of silicone polymer with water and hexadecane are 85 to 90 degrees and 30 to 35 degrees respectively. Comparing those indicators, it is obvious that releasability of silicone polymer is far inferior of that of fluoropolymer. For the above, there is no alternative to fluoropolymer. It is the only material of choice for toner-fusing films/belts. The major world-wide printer/photocopier manufactures include Canon, Brother, HP, Kyocera, Fuji Film, Ricoh, Konica Minolta, Sharp., etc. World-wire sales quantities of printers and photocopiers in 2021 are 27,280,000 units and 3,460,000 units respectively. The annual combined sales of the printer/photocopier industry are approximately 19 billion euro. About 30% of the total sales quantities come from the EU countries. Therefore, the economy size of estimated 6 billion euro could be affected. The size of the workforce of the printer/photocopier industry in the EU countries, including manufacturer, part/material suppliers, retailers/distributers, is estimated to be approximately 500,000 workers. The magnitude of the effect on the EU labor market is significant. SEMICON APPLICATIONS FLUOROTUBING TUBES Fluorotubing, known for its unique properties of chemical resistance, are widely used for delivering liquids in high-tech applications. These tubing are connected and installed to storage tanks that contain harsh chemicals such as hydrogen fluoride (HF) or hydrogen peroxide (H2O2). These chemicals are crucial for rinsing semiconductor processor chips used in computers and other semiconductor applications in order to purify their surfaces. Purification and achieving ultimate purity, along with chemical resistance, are paramount in adopting tubing for these high-tech applications. Without these specialized tubes, the economical and efficient production of microprocessors would be jeopardized, as computer chips cannot be produced without thorough cleaning with hydrogen fluorides and/or hydrogen peroxides. There are five objects that need to be purged from the semiconductor materials during the rinsing process: Particles Metal ions Organic matter Oil Oxide film None of these objects should be eluted or found before etching a microprocessor chip, as the purity of the chemicals and surfaces is crucial to ensure the quality of the final product. Due to its unique characteristics, Fluortubing is the ideal solution for maintaining the purity of the chemicals during the delivery process. Fluortubing does not react with the chemicals and does not release any metal ions, making it the only suitable material for this application. The delivery hose must also be pure and stable, as it should not introduce contaminants or react with the chemicals being transported. In conclusion, Fluortubing is essential for the safe and efficient delivery of harsh chemicals used in semiconductor manufacturing. Its unmatched properties of chemical resistance, purity, and non-reactivity make it the preferred material for ensuring the high-quality and purity of semiconductor materials during transportation and processing. |

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| 8159 | Date:  2023/09/21 10:56  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sang-A Frontec  Org. country:  Korea, Republic of | General Comments:  SANG-A FRONTEC CO.,LTD is a company that specializes in processing fluoropolymers in Korea We request that fluoropolymer such as PTFE and PFA parts in home appliances (microwave, oven) be completely excluded from ECHA's PFAS restrictions.  The consumption of all PTFE types worldwide and in western Europe is 190 and 35 Mio. kg respectively. The suspension PTFE market 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 chemical resistance, hydrophobic properties, excellent dielectric properties, amongst many others. This makes it an extremely valuable materials for the use in many different industries.  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, specialized products at high costs. 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. PTFE is not used for conveniency, but for high-end products where a certain combination of properties is really necessary (essential use!). |
| Answer to specific info request 6:  PTFE PFA Parts for microwave and oven range. PTFE or PFA parts are essentially used as gauge dials, guide rollers, holders, and shafts because PTFE, PFA are electrically and thermally stable and have low friction. |

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| 8160 | Date:  2023/09/21 10:59  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |

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| 8161 | Date:  2023/09/21 11:01  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment: | General Comments:  see attached |
| Answer to specific info request 1:  see attached |
| Answer to specific info request 2:  see attached |
| Answer to specific info request 3:  see attached |
| Answer to specific info request 4:  see attached |
| Answer to specific info request 5:  see attached |
| Answer to specific info request 6:  see attached |
| Answer to specific info request 7:  see attached |
| Answer to specific info request 8:  see attached |

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| 8162 | Date:  2023/09/21 11:04  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Maflow BRS  Org. country:  Italy  Attachment: | General Comments:  See attachment |
| Answer to specific info request 1:  See attachment |
| Answer to specific info request 2:  See attachment |
| Answer to specific info request 3:  See attachment |
| Answer to specific info request 4:  See attachment |
| Answer to specific info request 5:  See attachment |
| Answer to specific info request 6:  See attachment |
| Answer to specific info request 7:  See attachment |
| Answer to specific info request 8:  See attachment |

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| 8163 | Date:  2023/09/21 11:07  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |

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| 8164 | Date:  2023/09/21 11:24  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  KAMAX Automotive GmbH  Org. country:  Germany | General Comments:  KAMAX Group is a global leading manufacturer of high-strength fasteners and a competent partner for the development and production of complex cold-formed parts. Over €1000 million turnover, 4,000 employees at 19 locations worldwide, 196,000 tons of steel per year equals 3.1 billion fasteners and complex cold-formed parts. The majority of these fasteners are used in the automotive sector, also for safety-relevant applications. Different Coatings are applied to the surface of these fasteners to adjust the friction coefficient for the respective requirement and to protect the products from corrosion in the long term. Up to four different layers can be applied in a complex process to achieve these properties. Approximately 80 different coating systems from various manufacturers are used in this process. The development, testing and approval of these coatings is a time-consuming and expensive process. According to conservative estimates and research, we assume as of today that approx. 70% of all coatings used may contain PFAS compounds. A large number of the substances covered by the restriction are not classified as hazardous substances under the CLP Regulation. Since the manufacturers of coatings are not obliged to pass on information about non-hazardous substances in the supply chain, it is difficult at this stage for a company like KAMAX to estimate the actual extent to which we are affected. Mainly polymers based on PTFE are used in these coatings. In order to compile all the relevant information for an exemption from the basic PFAS ban - especially for PFAS applications for which no alternatives currently exist or are not even foreseeable – KAMAX will need a reasonable amount of time. For example, since data on socio-economic impacts of the restriction must first be collected as part of comprehensive studies along the entire supply chain. Replacing these substances in an estimable time frame represents a considerable effort in terms of personnel in R&D, application technology and production.  Besides the product related coatings KAMAX does use PFAS relevant media in its processes. In detail, these are the following groups of materials:  • Lubricants in use for cold forming • Cooling lubricants for use in machining applications • Additives and ingredients in the phosphating process • Special sprays and operating materials for maintenance and servicing  These numerous media in use by the KAMAX Group have not yet been analyzed to determine whether they are affected. This may vary at different production sites and may be sourced from local suppliers. There is currently no overview of this type of material, gathering the information is time-consuming. |
| Answer to specific info request 1:  Use in coating materials as a surface additive to adjust particularly smooth surfaces or surfaces with specific properties (coefficients of friction) for customer application. In the assembly of chassis and wheels, for example, safety-relevant fasteners (e.g. bolts, nuts, washers, clips, etc.) are used whose functionality can only be ensured by coatings with fluoropolymers according to the current state of the art. The coating ensures that the required defined assembly condition (including pretensioning and clamping force) is met, so that the connection retains its function and the necessary safety. In these safety-relevant applications, no adequate alternatives are currently available, nor can they be found and established within the planned transition period. |
| Answer to specific info request 2:  The PFASs are firmly embedded in a very thin layer of 5-10µm of coating on the surface of the fasteners, so there is no release if used properly. In principle, the coatings for bolts are applied in very thin layers. In the following observation, the composition and the content of Polymeric PFAS of the coating is known. The calculation example shows how low the PFAS content is in the coating of bolts screws. However, the resulting surface properties represent an enormous technical significance for the function of the component: Amount of coating material per screw: approx. 0.058g (dry film) Weight percentage of PFAS approx. 4%. Weight of bolt: 87g PFAS per bolt: 0.0023 g % PFAS per bolt: 0,0026% Unfortunately, we do not have any data on loss rates due to weathering or abrasion. Furthermore, we are not aware of any emissions of PFASs at the end of the life cycle of the fasteners. |
| Answer to specific info request 5:  Coated fasteners could fall under classification for lubricants according Paragraphs 5s if sliding coatings are also the focus of this exemption. As mentioned in question 2, that the PFASs are firmly embedded in the coating, so there is no release if used properly. Exact data are not available at the moment. Due to the lack of detailed information of our suppliers and of the manufacturers of the used coating systems, we are not able to provide information about the annual used tonnage of PFAS on our products. In this regard we also refer to our example calculation shown in our answer to request 2. The identification of those elements and related effects is still ongoing. |
| Answer to specific info request 6:  As already described in general comment, bolts and fasteners produced by KAMAX are mainly used in several automotive applications, also for safety related parts, for example in chassis applications, braking systems and wheels. Currently no functioning alternative known – R&D of coatings has to happen at the coating suppliers first (Because of the broad variety of coatings they may not be able to do all necessary developments in parallel). Once new alternative coating developments projects (by coating suppliers or jointly coating suppliers and manufacturer of fasteners) will be successfully concluded, KAMAX has to qualify them for their processes and their applications (1-3 years). Finally the customer has to qualify the coatings for his applications (2-3 years). The costs to be expected for this are obviously up to 100.000Euro per each development and coating product. It can be assumed that these costs cannot be passed on with the fastener sales to e.g. OEM customers. An example of a safety-relevant component is the coating of chassis bolts. These must have a defined friction coefficient (e.g. VDA friction coefficient window). To achieve this, the bolts must be smooth enough on one side to be easily screwed in. On the other hand, they must not be too smooth so that they loosen on their own, for example while driving, and thus the chassis falls apart while driving, or the head of the screw is turned off during the tightening process. Furthermore, the surface must not be too rough, otherwise the bolt will jam in the worst case and cannot be completely screwed into the chassis. PFAS are ideal and currently without alternative as a component of the lubricant in the bolt coating to reliably guarantee this adjustment of the coefficient of friction. This application affects practically all automobile manufacturers. As no alternatives are yet known, the loss of supplies of bolts is threatening the entire automotive industry. |

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| 8165 | Date:  2023/09/21 11:25  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |

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| 8166 | Date:  2023/09/21 11:26  Content:  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  <redacted>  Org. country:  Finland  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors, Electronics |
| Answer to specific info request 6:  Please find requested information in attachment "SECTION V. Confidential Attachment". |