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:
   a. 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.
   b. 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.

3. **Emissions in the end-of-life phase**: With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

4. **Impacts on the recycling industry**: To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:
   a. 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).
   b. The measures that recyclers would need to take to achieve the proposed concentration limits.
   c. The costs associated with these measures.

5. **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.

6. **Missing uses – Analysis of alternatives and socio-economic analysis**: Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:
   a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
   b. The key functionalities provided by PFAS for the relevant use.
   c. The number of companies in the sector estimated to be affected by the restriction.
   d. 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.
   e. 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.
   f. For cases in which **substitution is technically and economically feasible** but more time is required to substitute:
      i. 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);
      ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
      iii. 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);
      iv. information on the benefits for alternative providers.
   g. 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.

7. **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.

8. **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.

9. **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.

10. **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.

4108	**Date:** 2023/05/15 10:47	**General Comments:** This is the corrected version and refers to number: 4307dc9c-11b4-4810-8763-3d4ce80794f8
	Type: BehalfOfAnOrganisation **Org. type:** Company **Org. name:** VITLAB GmbH **Org. country:** Germany **Attachment:** ref_4108_public.pdf	**Answer to specific info request 6:** Due to insertion errors, mistakes crept in and therefore we would like to correct the old entry (4307dc9c-11b4-4810-8763-3d4ce80794f8). Here the correct version: Table A.1 in Annex A of the Annex XV Restriction Report lists in blue highlighted PFAS uses that have not been addressed in further detail, such as laboratory equipment. This includes, in our understanding, all laboratory equipment, e.g. equipment that is used in an analytical laboratory for product analysis in the food industry as well as in the pharmaceutical or petrochemical industry. The equipment is required for reliable examination of product quality and confirmation of product safety. These instruments are also needed to analyse various environmental samples (e.g. soil, water, ...). These can be spectrometers, chromatographs, dosing systems, burettes, pipettes or simply beakers, volumetric flasks, sample vials or tubes. We expressly emphasise that these products are intended for industrial use and have no application in the private environment. a The laboratory market is a small but important market and has only a minor share of the 840000 tonnes of PFAS that enter the market annually. For our company, we process barely 2 tonnes of the fluoropolymer PFA p.a., which then go to the market as volumetric flasks, beakers and bottles. We cannot provide annual emissions. The waste generated during the manufacturing process is added back to the process directly at the machine, so that almost no plastic waste is produced. The manageable residual quantities go to certified disposal companies. b The most important functions provided by PFA for the respective application is its high temperature resistance and chemical inertness. The raw material used is also particularly clean and contains no catalyst residues worth mentioning, a basic condition for to production of products for metal trace analysis. c The number of companies manufacturing these products in the laboratory sector in Europe in particular and throughout the world is very limited. Besides us, there are perhaps less than ten manufacturers of these special laboratory devices in the world. d There is no alternative material with equally good chemical properties. This is the state of the art and it is very likely that there will no such equivalent material in future providing the same chemical features. However, there are alternative materials that could be used, but these materials offer poor performance and have a significantly shorter usage period. When dealing with highly corrosive media, such as concentrated acids (HNO_3, H_2SO_4, ...) or hydrofluoric acid (HF), which are used to digest solid samples, all other materials will quickly be destroyed or cannot be used at all (e.g. glass in the case of HF). The other materials also negatively affect the subsequent analysis due to contamination. This creates the risk of inaccurate analysis and incorrect analysis results. e As the availability of alternative materials is not yet given and whether and when such a material will be available, it is also not yet possible to estimate whether supply problems with the potential alternative materials could be expected. f We process currently the available material, which is produced

		by the chemical fluoropolymer industry. We have no data or indications whether the polymer manufacturers are already researching alternative materials and if and when an alternative could be expected. Therefore, as downstream user, we cannot provide any information regarding the following two points below. i.; ii.; iii. All currently available materials beside PFA are limited in their functionality and this may course that users in the pharmaceutical analytical quality laboratory have to change a flask made of other materials more frequently. This will course significantly higher effort. This is not only leading to increasing costs for analytics, but also results in much higher amount of waste material. As the determination of specific toxic substances would no longer be possible on today's quality level the consumer would also be negatively affected due to lower quality of analysis (e.g. toxic substances eating food stuff). iv. We do not have information regarding benefits of alternative providers. g Commercial impact (no alternative material given): The business impact for manufacture (VITLAB) would be -1.500.00 € turnover and five employees. Other manufactures: no information Customers: no information (but noticeable cost increase)

4109	**Date:** 2023/05/15 10:54 **Content:** Scope or restriction option analysis Hazard or exposure Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Mitsubishi Chemical Advanced Materials NV **Org. country:** Belgium **Attachment:**	**General Comments:** In following this grouping approach, the proposed PFAS Restriction would restrict PFAS that have not been risk-assessed and for which an unacceptable risk has not been demonstrated, in breach of Article 68(1) REACH. Article 68(1) REACH provides that substance(s) can be restricted only if they pose an unacceptable risk to human health or the environment. This unacceptable risk must be positively demonstrated by conducting a risk assessment that follows the conditions of Annex XV to REACH (and by cross-reference of Annex I and Annex XIII). Such risk assessment comprises hazard identification and characterisation, exposure assessment and risk characterisation. By grouping all various PFAS substances together and restricting them as a single class, the proposed PFAS Restriction Proposal would restrict numerous PFAS substances that have not been risk-assessed and for which no unacceptable risk has been demonstrated, in breach of Article 68(1) REACH. More specifically, the scope of the proposed PFAS Restriction is based on the OECD definition of PFAS. That definition is only based on chemical structure and does not take into account hazardous properties or risks of PFAS, as the proposed Restriction itself acknowledges (p. 19). As a result, it covers approximately 10,000 substances with very diverse physical, chemical and biological properties and behaviour. That broad definition does not take into account the specific, distinct properties of different individual PFAS or PFAS subgroups and is therefore not suitable for regulatory risk management purposes.

	ref_4109_public.xlsx	OECD itself acknowledges that this definition "does not conclude that all PFASs have the same properties uses, exposures and risks" and that it can only serve a starting and reference point as it "may be viewed as too broad" (OECD, 2021, Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance). In particular, the very broad scope of proposed Restriction –which is based on the OECD PFAS definition- does not enable a legally and scientifically sound risk assessment. By grouping all PFAS together in a single group for risk assessment, the proposed Restriction fails to identify and consider the specific, distinct properties of each individual PFAS or PFAS subgroup and, in turn, to assess and characterise the hazards and risks related to those properties in order to demonstrate that they pose an unacceptable risk to human health or the environment. For example, fluoropolymers are thermally, biologically, and chemically stable, barely soluble in water, immobile, insoluble (Water, Octanol, etc.), and too large to migrate to cell membranes, so they are not incorporated into the body and are considered low concern from a human and environmental health perspective1,2. The findings demonstrate that fluoropolymers are a distinct group from PFOA and PFOS and should not be combined with them for hazard assessment or regulatory purposes. Fluoropolymers are the only materials that simultaneously possess heat resistance, weather resistance, chemical resistance, water repellency, lubricity, and unique optical/electrical properties, and they have become indispensable materials in many fields, including the energy field (Fuel cells and lithium-ion batteries), semiconductor field (Clean members, etching gas), electrical and electronic communications field (Wire cladding and liquid crystal materials), transportation field (Cars, airplanes, railroads), and medical field (Catheters, protective clothing). It is necessary to carefully re-examine whether the uniform regulations for PFAS are appropriate in light of the chemical hazards and risks of the substances in question. In particular, fluoropolymers should be excluded from the current regulations because they are highly stable materials and have no concerns about bioconcentration or toxicological effects. Reference: 1: Barbara H et al., Integrated Environmental Assessment and Management, Vol14(3), p316–334. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035 2: Stephen K et al, Integrated Environmental Assessment and Management, Vol19(2), p326–354 https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4646

		Position is shared with Conference of Fluoro-Chemical Product Japan (FCJ)
		Answer to specific info request 1: See file 'PFAS_overview_ECHA.xlsx'
		Answer to specific info request 6: See file 'PFAS_overview_ECHA.xlsx'

4110	**Date:** 2023/05/15 11:03 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** MITSUI E&S Co.,Ltd. **Org. country:** Japan	**General Comments:** We are manufacturer of reciprocating compressor which is used for oil & gas market, and it is mainly applied for hydrocracking in refinery. Recently, our compressor has availability to apply wide range of new energy business such as electrolyzer, fuel cell, sustainable aviation fuel(SAF), carbon capture and storage (CCS) and others. Reciprocating compressor has a lot of sealing parts, and PTFE is a one of popular base material for sealing parts, and restriction of PFAS will impact to design of sealing parts of compressor, and it is connect to reducing of production in facilities where our compressor is applied such as refinery and other in oil and gas market, and new energy business market.
		Answer to specific info request 1: E.2.15
		Answer to specific info request 6: b. sealing parts of compressor (parts names are piston ring, rider ring, piston rod packing) c. uncountable (oil and gas company, compressor manufacturer who mainly provide for oil and gas market, sealing parts manufacturer, and others) d. There are alternatives such as PEEK and others, however, depends on application of compressor, PTFE is best choice to ensure longer service life, and other alternative causes reduction of service life of equipment, and increasing of maintenance cost of equipment and facilities. e. PTFE is the highest improvement which is considered for the current market, and it is not sure how much duration is required for new development which can supply same quality with PTFE. g. see above c and d.

4111	**Date:** 2023/05/15 12:20 **Content:**	**General Comments:** Our company supplies safety-critical transfer devices to several different markets and these are typically used in the transfer of potentially explosive, potent, and sterile powder ingredients - requiring high containment or sealing. These markets include pharmaceutical, food, medical, battery production &

	Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** United Kingdom **Company name confidential:** Yes **Privacy statement:** All information provided could impact the business commercially so would like it to remain confidential. Any release of information should be discussed with myself first	metallic powder transfer – all of which require specialist equipment to ensure the safety of the operator or powder being transferred. A key requirement of the device is utilising effective sealing materials such as PTFE, FKM and FFKM seals. Our customers are global and span multiple sectors, ranging from small-scale drug discovery and development to major international pharma companies. The devices and the materials used go through rigorous process validation and control procedures as part of our customers' manufacturing implementation and management. The seals manufactured from PTFE/FKM/FFKM are a critical element of these validation processes. Many of the processes in question use chemicals (e.g. toluene, methylene chloride, methyl isobutyl ketone) that require superior chemical compatibility to other certified materials available as alternative. Using any of these alternatives would provide inferior chemical compatibility and therefore would result in unsafe and unreliable devices with a dramatically increased risk around operator and product safety. The device seals are in direct contact with the products within a safety and process critical device, meaning that any change in product or manufacturing process requires our customers to follow a rigorous change control process including re-validation. This is to mitigate any risk in relation to process operators and ultimately, potentially, patients taking the end drug product - oral or injectable. Because of this, we have agreements in place with our customers that, pharmaceutical customers especially, require a minimum 6 month notice period for any changes in material, manufacturing processes, device construction or operation to enable an appropriate amount of time to safely transition ensuring the right validation has been completed (including FDA compliance, USP VI 88 & 87, Triboelectric testing to EN ISO 80079-36:2016 & EN 60079-32-2:2015), even when implementing material of "equivalent" grade. For our customers, the continued use of FFKM/FKM/PTFE is critical to the safety of the products they are producing and without an exemption for ourselves (as manufacturers) and our suppliers (as distributors) there is a risk that our customers will not be able to continue production and risk the safety of products across a range of industries – a key sector being pharmaceutical products being used directly by patients.
		Answer to specific info request 1: Food contact materials and packaging & Plastic Packaging Medical devices & Packaging of medical devices
		Answer to specific info request 6: We have companies using our equipment within the following sectors as well as the medical/pharmaceutical/food mentioned above: - Nuclear waste handling and transfer - Battery production - Energy sector
		Answer to specific info request 8:

		For our customers, the alternatives are unknown as there does not seem to be a known way of achieving the same or similar chemical compatibility with a certified material (or a material that is able to be certified).

4112	**Date:** 2023/05/15 12:43 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes **Attachment:** [redacted] **Privacy statement:** We want to keep the usage of PFAS confidential.	**General Comments:** Regulatory bans on PFAS used in equipment and materials for chemical manufacturing, for example fluoropolymers and refrigerant F-gas, for which there are no alternatives, would make manufacture of many chemicals impossible, and the impact on many applications would be serious. Consequently, PFAS used in equipment and materials for chemical manufacturing, for example fluoropolymers, F-gas should be excluded from the restriction of PFAS. **Answer to specific info request 1:** Chemical industry (Chemical manufacturing) is missing from the proposed restliction as an application.

4113	**Date:** 2023/05/15 12:43 **Content:** Request for exemption **Type:**	**Answer to specific info request 1:** - TRASPORTATIONS: Land (cars, trucks, trains, all vehicles) and Marine (Bridge bearing supports). - GENERAL INDUSTRIAL, machine constructions. - CHEMICAL INDUSTRIES (pumps’ components, seals, gaskets, etc). - AUTOMOTIVE INDUSTRY. - SEMICONDUCTORS INDUSTRY. - HIGH VOLTAGE APPLICATIONS. - OIL AND GAS PRODUCTION. - ALTERNATIVE ENERGIES (H2) - AEREOSPACE INDUSTRY. - MILITARY INDUSTRY. - MEDICAL AND PHARMACEUTICAL INDUSTRY. - GAS AND LIQUID

	BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Fluorten S.r.l. **Org. country:** Italy **Attachment:** [redacted]	FUEL TRANSPORTATION. - ELECTRONICS AND CHIPS PRODUCTION INDUSTRY. - VALVES PRODUCTION (Sealing elements). - ATOMIC / NUCLEAR ENERGY: Both production and Research Institutes. **Answer to specific info request 8:** All possible info in the attached files

4114	**Date:** 2023/05/15 15:35 **Content:** Scope or restriction option analysis Hazard or exposure Environmental emissions Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Germany **Company name confidential:** Yes	**General Comments:** The answers given below are short summaries for the information given in the confidential attachement. For detailed information on the answers and references please take a look at the confidential attachement. Scope and restriction analysis Fluorpolymers used as fluororubber and PTFE from us are handled in a very high range (such as Intake Manifold Gaskets, Oil Sumps, Valve Cover Gaskets, Sealing Elements for Cylinder Head Covers, Partial Coationgs for Cylinder Heat Covers, Sealing Lips of radial shaft sealing rings, O-Rings). Hazard and exposure Outgoing from fluoropolymers there are no exposures for human (can not cross cell membranes) and environment. Fluoropolymers fulfill the criterias for being classified as polymers of low concern and include negligible hazardous residual monomers. The only "hazard" outgoing from the fluoropolymers is the persistence which is expressly desired for the safe use of vehicles (and thus a benefit in that case). Environmental emissions There are no emissions outgoing from fluoropolymers used for automotive applications into the environment. In addition, fluoropolymers used in the transport sector as gaskets or sealings avoid the emission of non-polymeric hazardous substances because of their barrier function and inertness. Without the usage of fluoropolymers in this sector, the achievement of the climate protection targets will be endangered. Environmental emissions from PFAS in Li-Ion-batteries are not expected because in their function as a binder they are in a closed system and the batteries itself are getting recycled.

	Attachment: [redacted] **Privacy statement:** According to Article 4(2) of Regulation 1049/2001, we want to keep the attached contents in section V confidential for protecting the commercial interests.	Information on alternatives For the fluoropolymers which are used in the motor area for sealing applications are no alternatives available, because the material must have a very high stability/ persistent properties next to mechanical strength (higher 8 MPa), wear resistance, flexibility, resistance to high temperature (higher 200°C), fire retardancy, non-stick properties and a low coefficient of friction. Information on benefits Regarding fluoropolymers in the transport section: Less maintenance and lower risk of unexpected failure of propulsion systems. The lifetime of fluoropolymers is much higher than other elastomer classes especially for thermo-oxidative resistance, heat resistance and chemical resistance. A lot of existing propulsion systems in different sectors of the economy need to be replaced with new systems or can´t be operated anymore because the replacement gaskets might not be allowed to be produced anymore (disruption in transportation sector for people and goods, food sector because of agricultural equipment, resource mining and harvesting). Other socio-economic (SEA) issues Replacing fluoropolymers in the transport sector would lead to a huge frequency of maintenance and repair cycles. High costs and unclear timelines if and until when alternative solutions can be found. Request for exemption Fluoropolymers should be excluded from the PFAS-restriction.
		Answer to specific info request 1: Use Sector: Transport (Annex E.2.10.) • Use of PFAS in applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this proposed restrictions (e.g. under lubricants, electronic equipment and TULAC) Sub-uses: Sealing and hose applications in stationary and especially mobile propulsion systems as well as in fuel cells and electrolyser applications (e. g. PVDF is used as a cathode binder in Li-ion-cells); also power electronics, traction batteries. Examples for mobile propulsion systems are cylinder head gaskets for combustion engines for heavy duty trucks, ships, big construction, agcricultural and mining machines, fuel cells in various usages and electrolysers for hydrogen production ect. More examples: Fuel management systems (spring energized seals); electric drive units (radial shaft seals); brake systems (guiding rings, special sealings). Use Sector: Energy

		Sector (Annex E.2.12.) • PEM Fuel Cells, PEM Electrolyzers • Li-Ion-Cells: PVDF is used as cathode binder
		Answer to specific info request 2: For detailed information on the answers and references please take a look at the confidential attachement. a) Regarding the fluoropolymer sector: • Manufacture & Processing Phase: approx. 0 % • Use Phase: approx. 0 % • End-of-life Phase: approx. 100 % b) The fluoropolymer waste can be divided up into the groups "scrap" and "rubber waste". The rubber waste-fraction goes to the thermal utilization and the scrap will be supplied to the scrap-recycling. The BEST4Hy project deals with the recycling of end-of-life PEM and SOFC fuel cells. Producers of fuel cell stacks as well as recycling companies from the private sector and scientific institutions such as universities are involved. Publications show that it can be assumed that up to 80% of the ionomer (TRL3 - TRL5) in PEM fuel cells can be recycled.
		Answer to specific info request 3: For detailed information on the answers and references please take a look at the confidential attachement. The products formed by incineration of fluoropolymers depend (among others) on the incineration temperature. In general, the four main types of incineration products formed are fluoroalkanes, hydrogen fluoride, oxidation products and fluoropolymer particle matter. The formation of decomposition/ incineration products can be adjusted, so that the formation of PFAS can be reduced to a minimum in incineration processes.
		Answer to specific info request 4: For detailed information on the answers and references please take a look at the confidential attachement. Regarding Li-Ion-Batteries: The economic viability for PFAS-recycling in batteries is not given because the total amount is less than 1 %, especially regarding the concentration limits proposed in paragraph 2 of the proposed restriction entry. Regarding fluoropolymers: Regarding the concentration limits proposed in paragraph 2 of the proposed restriction entry, recycling of fluoropolymer waste will only be economically viable – if at all – in a big scale. Regarding PEM fuel cells, PEM electrolyzers: No information available.
		Answer to specific info request 6: For detailed information on the answers and references please take a look at the confidential attachement. Fuel cells play a crucial role in zero-emission driving and – together with electrolysis – the key to storage of regenerative electricity for prolonged periods of time. If successfully introduced to the market, about 200,000 fuel cell vehicles (each 200 kW) are expected globally by 2030. Assuming a membrane area of 16 m² per car, about 128 t of PFSA materials would thus be needed to produce the proton exchange membranes. For a more optimistic scenario with 1 million vehicles on the road a total

		of 640 t results accordingly. This value represents only the membrane but does not yet include the proportions of additional PFAS materials in necessary components such as seals. In terms of membrane area, an annual expansion of electrolysis capacities of 10 GW per year by 2030 would require about 40 t/a of PFSA materials. On a maximum scenario of 40 GW per year, 160 t/a would be required.
		Answer to specific info request 7: For detailed information on the answers and references please take a look at the confidential attachement. Use Sector: Transport (Annex E.2.10.) • Use of PFAS in applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods (Paragraph 6 o)) Key functionalities: vehicle safety, reliability at high temperature fluctuations, all kind of resistances (chemical against a wide range of media, thermical up to 220 °C, biological), inflammability, resistance against friction and closure, high permeation density, low coefficient of friction, excellent mechanical properties, excellent barrier properties, non-stick properties. These functionalities are essential for the use in applications affecting the proper functioning related to the safety of vehicles, operators, passengers or goods. Consequences: high life cycle (up to 22 years), low damage rates, safe sealing and transport of several service liquids, low emissions of hazardous products and substances, achievement of the climate protection targets. In addition, PTFE should replace N-Methyl-2-Pyrrolidone as a coating material. In comparison to N-Methyl-2-Pyrrolidone, PTFE is not toxic to reproduction, so replacing N-Methyl-2-Pyrrolidone to PTFE would mean a substitution to a substance which is not harmful to human health. There isn't known a fluorine-free alternative material with comparable properties and it is very unlikely that an adequate fluorine-free material alternative can be developed at all. Other polymers (e. g. PEEK, PU) do not allow the combination of the properties described above. If the use of fluoropolymers would be restricted this would directly or undirectly affect all the companies in the transport sector where in sum about 3.5 million people are employed. It is expected that the transport sector would be hit severly by such an act.
		Answer to specific info request 8: For detailed information on the answers and references please take a look at the confidential attachement. The ambitious targets for reducing CO2 emissions in the European Union towards climate neutrality in connection with the Green Deal and the Fit for 55 program require rapid and far-reaching measures with regard to the energy transition in almost all sectors, from the production of steel, for example, to heating in private households and mobility. The European Union has recognized that the transformation to climate neutrality can only succeed if a hydrogen economy can be successfully established in the EU. The EU Commission defined this in 2020 within the so-called hydrogen strategy for the vision of creating a hydrogen ecosystem, starting with research and innovation and extending to production and infrastructure. Hydrogen thus plays an important role in the decarbonization of industry

		and heavy transport in Europe. Specifically, the European Union aims to have a production capacity of 10 million tons of hydrogen per year by 2030 from 500 TWh of electricity produced by electrolysis. This is equivalent to about 14% of the EU's total electricity consumption and thus requires an enormous ramp-up of hydrogen technologies.

4115	**Date:** 2023/05/15 17:14 **Content:** Information on alternatives Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** RUDOLF GROUP **Org. country:** Germany **Attachment:** ref_4115_public.pdf [redacted]	**Answer to specific info request 1:** Information on uses in the field of specific textiles. Please find the details in attached document. **Answer to specific info request 2:** C6 fluorinated polymers are usually applied by pad application onto the textile fibre. In this application a roll of untreated fibre is led through a bath with C6 fluorinated polymer solution. Upon pick-up of the finishing liquor, the excess water is squeezed out by padding. From our experience, textiles applied by this method contain about 1.0 wt% C6 fluorinated polymer relative to the textile fibre weight. Please refer to our confidential submission part for detailed information on how this number converts to potential emissions of PFHxA-related substance. However, it has to be taken into account that treated articles are usually made up of more than one fabric layer. So, it is expected that less than half of an outdoor jacket consists of fabric material treated with C6 fluorinated polymer. Furthermore, C6 fluorinated polymers are tightly bound to the textile fibres by cross-linkers in washable articles. Hence, only a small fraction of the C6 fluorinated polymer can be extracted by chemical methods. **Answer to specific info request 3:** Please see confidential information in the respective confidential ttache **Answer to specific info request 6:** If the timeframe was too short, it would be impossible to develop fluorine-free technologies for the technically more advanced and challenging applications and, ultimately, these applications would be lost as well as jobs and markets associated with them. We estimate that more than half of our business with C6 fluorinated polymers goes into technically advanced applications. Hence, if Rudolf was not given enough time to transition the latter applications into fluorine-free solutions we estimate business losses to the number provided in the confidential submission part.

4116	**Date:** 2023/05/15 17:25 **Content:** Hazard or exposure	**General Comments:** SBM OFFSHORE is a customer using final product made of PTFE for sealing application. There are 3 reasons for overall chemical stability of fluoropolymers: The C-F bond is the strongest bond in organic chemistry The perfect shielding of Carbon backbone by big fluorine atoms make chemical attack impossible

	Environmental emissions Baseline Information on alternatives Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Netherlands **Company name confidential:** Yes **Attachment:** ref_4116_public.xlsx	The absence of end-groups due to ultrahigh molecular weight makes chemical attacks from the ends impossible. There is no alternative, please refer to appendix (table). **Answer to specific info request 1:** Energy sector and Petroleum & mining sector **Answer to specific info request 2:** A concept is being studied to put old seals in incineration to minimize emissions in end-of-life and leading to only minerals and energy recovery. SBM program is safe even at end-of-life. **Answer to specific info request 3:** SBM as a Company like for CO_2 emission reduction is working on fluorine emission reduction. Energy recovery with mineralization converting to fluorspar (CaF_2). **Answer to specific info request 4:** Refer to Survey on fluorowaste stream in Europe 2020. The majority of fluoro products after end-of-life are used for energy recovery by incineration. **Answer to specific info request 5:** 12-year derogation is a minimum required. SBM being a customer, user of final product made of PTFE, PFAS emission is null or close to null. **Answer to specific info request 6:** a. It represents 3 to 4 tons of PTFE and 4 to 5 tons Mod-PTFE per year with an average life-time of 5 to 20 years (long-term application and not daily use). For information, the European consumption is 42,000 tons per year. b. PFAS is at the origin of the PTFEs which have Overall chemical compatibility, low friction and sealing ability, and mechanical compliance (deformation) c. The number of companies is 20 to 35 (from Supply Chain to end users) d. Refer to Appendix (table) with studied alternative which are not suitable for our applications mainly due to the lower chemical compatibility performance. e. There are no alternatives available today for our applications but also in the future due to chemical reason. f. The use of alternative will lead to increased maintenance time and to reduced production efficiency; and will have impact on the environment. g. No exact data available for that question. Offshore Oil and Gas Market will move out of Europe if we can not produce competitive systems anymore. **Answer to specific info request 7:**

		12-year derogation is a minimum required.
		Answer to specific info request 8: There are no alternatives available today for our applications but also in the future due to chemical reason. The use of alternative will lead to increased maintenance time and to reduced production efficiency. Offshore Oil and Gas Market will move out of Europe if we can not produce competitive systems anymore.

4117	**Date:** 2023/05/16 00:52 **Content:** Scope or restriction option analysis Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** NIPPON BALL VALVE CO.,LTD. **Org. country:** Japan **Attachment:** ref_4117_public.pdf	**General Comments:** I agree with the comment of the Japan Fluorochemical Products Council (FCJ).

4118	**Date:** 2023/05/16 03:28 **Content:** Scope or restriction option analysis Other socio economic analysis (SEA) issues	**General Comments:** Concerns about some fluorine compounds, such as bioaccumulation and toxicological effects The concern about some fluorine compounds, such as bioaccumulation and toxicological effects, is not appropriate to be considered for all perfluorinated organic compounds (PFAS) in general. (PFAS), and if the need for new regulations is considered in the future, the risks of each substance should be quantitatively evaluated and discussed.

	Type: BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Kurimoto Trading Co.,Ltd. **Org. country:** Japan **Attachment:** [redacted]	When the need for new regulations is considered in the future, the risks of each substance should be quantitatively evaluated and discussed. Translated with www.DeepL.com/Translator (free version)

4119	**Date:** 2023/05/16 04:05 **Content:** Scope or restriction option analysis Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes **Attachment:**	**General Comments:** Cashew Co.,Ltd. supports the statement made by FCJ on the issues of proposed restriction,as per attached in Section IV **Answer to specific info request 1:** Non-stick coatings in industrial and professional bakeware Use of PFASs in applications affecting the proper functioning related to the safety ofvehicles, and affecting the safety of operators,passengers or goods, to the extent not addressed under other parts of this proposed restriction(e.g. under lubricants,electronic equipment and TULAC) **Answer to specific info request 6:** a.The annual tontage:3t/y,emission:0t,type:PTFE b.Heat resintance and non-stick c.Over 1000 companies g.Cooking utensils that require heat resistance and non-stick properties cannot be used, which has a significant impact on energy efficiency and food waste.Automotive parts that require lubricity become unusable, which has a significant impact on safety.

	ref_4119_public.pdf	

4120	**Date:** 2023/05/16 04:35 **Type:** Individual **Country:** Japan	**General Comments:** 情報収集の為、登録させて頂きました。

4121	**Date:** 2023/05/16 08:25 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** FluoroTechnology Co.,Ltd. **Org. country:** Japan **Attachment:** ref_4121_public.pdf	**General Comments:** Water and oil repellent sprays used for shoes and sandals made of leather or canvas must have not only water repellency but also oil repellency from the standpoint of stain prevention. Oily substances such as cooking sauces and salad dressings soak into leather and fibers, causing stains. If leather products or silk Japanese clothes get dirty, cleaning is difficult and time-consuming. In some cases, these stains cannot be removed even by cleaning, and the product cannot be used. In order to avoid such troubles, it is essential to coat the surface with an oil-repellent fluorine-based substance. Various resins such as acrylic and urethane resins, as well as silicone-based compounds, can be considered as substitutes for PFAS in this application, but compounds other than fluorine-based compounds do not have oil repellency and cannot prevent stains. In addition, it cannot be used as a substitute for this application because of its poor water repellency.
		Answer to specific info request 1: Leather and textile protection (oil and water repellent)
		Answer to specific info request 2: There are no PFAS emissions during manufacturing and use. At the end of its useful life, the entire amount is disposed of, but almost all of it is incinerated and decomposed into HF, so no PFAS is released into the environment.
		Answer to specific info request 3:

		At the end of its useful life, the entire amount is disposed of, but almost all of it is incinerated and decomposed into HF, so no PFAS is released into the environment.
		Answer to specific info request 5: If we limit it to leather and silk products, we estimate that it is 100 to 500 tons each year.
		Answer to specific info request 9: There is no academic data that it is a precursor of these substances.

4122	**Date:** 2023/05/16 09:12 **Content:** Scope or restriction option analysis Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** NIPPON BALL VALVE CO.,LTD. **Org. country:** Japan **Attachment:** ref_4122_public.pdf	**General Comments:** I agree with the comments of the Conference of Fluoro-Chemical Product Japan (FCJ). Those comments are attached in Section IV.

4123	**Date:** 2023/05/16 11:08 **Content:** Request for exemption	**General Comments:** Coating agents that use fluororesin have acid resistance that other resins do not have . Therefore, it is widely used as an acid-resistant coating agent for metals. As an alternative substance, a coating agent obtained by dissolving a silicone resin, an acrylic resin, a

	Type: BehalfOfAnOrganisation **Org. type:** Company **Org. name:** FluoroTechnology Co.,Ltd. **Org. country:** Japan **Attachment:** ref_4123_public.pdf	urethane resin, an olefin resin, or the like in a hydrocarbon-based organic solvent can be considered. However, these alternative materials are not highly acid resistant and cannot protect metals such as silver and copper when exposed to volcanic gases and acidic substances such as nitric and sulfuric acids . Therefore, it cannot be used as a substitute for fluorine- based coating agents . Substitute coating agents require hydrocarbon-based organic solvents as solvents for resins. There is a risk of ignition due to sparks or static electricity, which may lead to an accident. Non-flammable, low-toxicity, low-odor fluorine-based solvents (HFE, HFC, etc.) can be used as solvents for fluorine-based coating agents, keeping the working environment safe and protecting workers.
		Answer to specific info request 1: Anti Acid Coating for metals
		Answer to specific info request 2: There are no emissions during the manufacturing stage. During use, the fluorinated solvent (HFE or HFC) used as a solvent is released into the environment. We estimate this to be 10 to 50 tons per year. Fluororesin is emitted at the time of disposal, but there is no emission of PFAS because it is differentiated into HF due to the high temperature of melting during metal recycling.
		Answer to specific info request 3: Fluororesin is discharged at the time of disposal, but since it adheres to metal, it is separated into HF by high temperature melting during recycling, and PFAS is not discharged.
		Answer to specific info request 5: As a coating agent, the annual production volume is about 10-60 tons. The breakdown is 8-50 tons of solvent and 2-10 tons of fluororesin.

4124	**Date:** 2023/05/16 11:50 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:**	**General Comments:** Request exemption of fluoropolymers for the use in analytical instruments from the proposed PFAS restriction.
		Answer to specific info request 1: See attachment in Section 5
		Answer to specific info request 2: See attachment in Section 5
		Answer to specific info request 3:

	Company **Org. name:** [redacted] **Org. country:** Austria **Company name confidential:** Yes **Attachment:** [redacted] **Privacy statement:** due to commercial interests of the company, including intellectual property	See attachment in Section 5 **Answer to specific info request 5:** See attachment in Section 5 **Answer to specific info request 6:** See attachment in Section 5

4125	**Date:** 2023/05/16 14:26 **Content:** Scope or restriction option analysis Information on benefits Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Fluortubing **Org. country:** Netherlands	**General Comments:** text **Answer to specific info request 5:** 200 ton per year **Answer to specific info request 6:** Fluortubing flexible hoses are used in Tudertechnica rubber hoses with PTFE liners, used for medical, Pharma, cosmetic and food applications. Value of these sales are multimillion euro's. The Fluortubing liners are in the rubber hoses because of the combination of chemical resistance, heat resistance, cleanability, no leachable components and fully inertness. For the PHARMA, COSMETIC, FOOD industry the tubes from Fluortubing are 100% PTFE which is is the only material that is: phthalates free; complies with 1907/2006/CE (REACH), with FDA 21 CFR 177.1550, with DM 21/03/1973, with USP class VI main requirements, with ISO 10993 -5:2009 and 11:2006, with REGULATION 1935/2004/CE, with REGULATION 10/2011/CE, with REGULATION 1245/2020/CE. No other liner material has the same physical and chemical characteristics Potential alternatives could be Steel & other metals, High nickel alloys, Polypropylene, PVC, Glass / Ceramics / Mica Polyether sulphone, Polyimide but they have absolutely the same not same chemical resistance, heat resistance, cleanability and inertness. There is no substitution product for PHARMA, COSMETIC, FOOD and CHEMICAL with the same characteristics. For the PHARMA, COSMETIC, FOOD industry must be considered the following regulatory approval /

		certification: phthalates free; 1907/2006/CE (REACH), FDA 21 CFR 177.1550, DM 21/03/1973, USP class VI main requirements, ISO 10993 -5:2009 and 11:2006, REGULATION 1935/2004/CE, REGULATION 10/2011/CE, REGULATION 1245/2020/CE. The approval time is in the range of 5 to 10 years if there is an alternative products. The social economic impact will be that Shutdown of certain product lines (with loss of respective sales) with plant resizing. Then move operations to non-EEA countries. If using my products as components, stop offering the specific product lines and most likely stop operations altogether making these liners the industry. Possible complete shutdown of the operation in 3 to 5 years. Competitors are based outside EEA. All sales will go to non-EEA competitors which are not subject to EEA ban. In General: PHARMA, COSMETIC, FOOD, PETROCHEM industries will be in most of case unable to manufacture their own products without PTFE liner rubber hose. Most of the PTFE liner rubber hoses cannot be substituted in the production of PHARMA, COSMETIC, FOOD, PETROCHEM products not only for the characteristics of the PTFE itself (CHEMICAL RESISTANCE, HEAT RESISTANCE, CLEANABILITY, INERT MATERIAL) but also under the point of view of a safe production process where PTFE liner rubber hoses are required
		Answer to specific info request 8: In General: PHARMA, COSMETIC, FOOD, PETROCHEM industries will be in most of case unable to manufacture their own products without PTFE liner rubber hose. Most of the PTFE liner rubber hoses cannot be substituted in the production of PHARMA, COSMETIC, FOOD, PETROCHEM products not only for the characteristics of the PTFE itself (CHEMICAL RESISTANCE, HEAT RESISTANCE, CLEANABILITY, INERT MATERIAL) but also under the point of view of a safe production process where PTFE liner rubber hoses are required

4126	**Date:** 2023/05/16 14:31 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** TEIJIN LIMITED	**Answer to specific info request 1:** Fluoropolymer applications

	Org. country: Japan **Attachment:** ref_4126_public.docx	

4127	**Date:** 2023/05/16 15:03 **Content:** Information on benefits Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Fluortubing **Org. country:** Netherlands	**General Comments:** Fluortubing PTFE tubing are essential for SEMICON Industry **Answer to specific info request 2:** We make PTFE polymer tubing, so there will be no emmisions at the end -of-life. PTFE does not break down to micro plastics **Answer to specific info request 3:** There are NO PFAS emmisions during the use of our tubings **Answer to specific info request 4:** Our Tubings can be recycled **Answer to specific info request 5:** about 200 tons PTFE per year, no PFAS emmisions. **Answer to specific info request 6:** PTFE tubing, known for its unique properties of chemical resistance, is 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 PTFE 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: 1. Particles 2. Metal ions 3. Organic matter 4. Oil 5. 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, PTFE is the ideal solution for maintaining the purity of the chemicals during the delivery process. PTFE tubing 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, PTFE tubing 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.
		Answer to specific info request 7: In conclusion, PTFE tubing 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.
		Answer to specific info request 9: Fluortubing tubes do not break down in the environment

4128	**Date:** 2023/05/16 15:41 **Content:** Information on benefits **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Fluortubing **Org. country:** Netherlands	**Answer to specific info request 1:** tubes and catheters
		Answer to specific info request 2: There are no emissions at the end of life of our tubes. The tubes are incinerated or recycled.
		Answer to specific info request 3: Our tubes are incinerated finally to HF and C02.
		Answer to specific info request 4: Fluortubing is working on PTFE recycling process.
		Answer to specific info request 5: Fluortubing uses about 200 tons PTFE per year
		Answer to specific info request 6: Fluortubing is a company that produces flexible hoses and tubings made of PTFE (polytetrafluoroethylene), a thermoplastic polymer with excellent chemical resistance to highly corrosive environments. These hoses and tubings are commonly used in the production of chlorine gas using alkaline electrolysis, which is a more energy-efficient and environmentally friendly method of production. In alkaline electrolysis for chlorine production, Fluortubing's PTFE tubing is used in the construction of the anode compartment and for transporting the chlorine gas. This material is resistant to chemical attack by the alkaline electrolyte, which can be up to 30% NaOH or KOH, and is also

		resistant to the highly reactive chlorine gas produced at the cathode. Additionally, PTFE tubing is flexible and can be easily formed to fit the desired shape and length of the anode compartment and the chlorine gas transport line. Using Fluortubing's PTFE tubing in alkaline electrolysis for chlorine production has several advantages, including durability, longevity, and sustainability. PTFE tubing has a long flex life, which means that it can withstand repeated bending and flexing without degrading, making it a durable and long-lasting material for use in the construction of chlorine production cells. In summary, Fluortubing's flexible hoses and tubings made of PTFE are essential for the European Green Deal's objective of creating a more sustainable and energy-efficient future for Europe. By using sustainable production methods like alkaline electrolysis and durable materials like PTFE tubing, Fluortubing is helping to contribute to this goal while also providing a reliable solution for the production of chlorine gas.
		Answer to specific info request 7: Fluortubing's flexible hoses and tubings made of PTFE are essential for the European Green Deal's objective of creating a more sustainable and energy-efficient future for Europe. By using sustainable production methods like alkaline electrolysis and durable materials like PTFE tubing, Fluortubing is helping to contribute to this goal while also providing a reliable solution for the production of chlorine gas.

4129	**Date:** 2023/05/16 16:22 **Content:** Scope or restriction option analysis Hazard or exposure Environmental emissions Baseline Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company	**General Comments:** We have prepared information on the topics selected above from the point of view of a processor (semi-finished product manufacturer of fluoropolymers). For a better overview, we have included these in the non-confidential attachment. Our fluoropolymer products are materials for the manufacture of process equipment, storage tanks or piping systems for handling aggressive chemicals at critical temperatures. Therefore, we are particularly critical of the fact that the chemical industry has not been included as a sector under Annex XV restriction report (Table 9). We address this in more detail in our response to Specific Information Request 6. Please also find this information in the non-confidential attachment.
		Answer to specific info request 6: Annex XV Restriction Report (Table 9) does not list fluoropolymer applications in the chemical industry. Please find the answers to the detailed questions in the non-confidential attachment.

	Org. name: SIMONA AG **Org. country:** Germany **Attachment:** ref_4129_public.pdf [redacted]	

4130	**Date:** 2023/05/16 17:03 **Content:** Scope or restriction option analysis Description of analytical methods **Type:** BehalfOfAnOrganisation **Org. type:** European institution **Org. name:** European Committee for Standardization CEN/TC 248 "Textile and textile products" WG 26 "Test methods for analysis of EC restricted substances" **Org. country:** Belgium **Attachment:**	**General Comments:** The restriction is not logical and clearly defined. Details are outlined in the following: 25 ppb for any PFAS as measured with targeted PFAS analysis The unit ppb does not appear useful. The unit µg/kg would be much clearer and will not be subject to any discussions on how to interpret ppb. ppb is no SI unit. A limit of 25 ppb (= 25 µg/kg) requires a test method with an appropriate Limit of Quantification (LOQ) that also takes the measurement uncertainty into consideration. For PFOA, PFOS and several other PFCA a sufficient low LOQ to verify compliance with 25 ppb in routine analysis is feasible. Using analytical instrumentation such as LC-MS/MS and GC-MS, GC-NCI-MS, GC-MS/MS available in market surveillance and third-party laboratories will not be sufficient to test for a number of PFAS because the LOQ for these substances is too high. For some substances it is above the proposed legal limit, e.g. LOQ of 4:2 FTOH: 400 µg/kg tested according to EN 17681-1:2022, see also the attached list PFAS including LOQ. We recommend to follow the approach for PFOA in the POP regulation, setting a legal limit of 25 µg/kg for the PFCA and PFSA that can be tested with an acceptable LOQ, except HPFHpA CAS 1546-95-8 which has a LOQ of 100 µg/kg when tested according to EN 17681-1:2022, and a legal limit of 1000 µg/kg for single PFSA and PFCA related substances such as n:2 FTOH. The limit for the sum of PFSA and PFCA related substances should also be set to 1000 µg/kg. It needs to be further outlined the only substances that are determined in a concentration above an LOQ as stated in a relevant EN standards should be included in the sum. In general, the legal text should reference to valid EN test standards for the related products groups because limits and especially limits of sums of substances are only useful with reference to the test method.

	ref_4130_public.pdf	targeted PFAS analysis It is outlined on page 9 that targeted PFAS analysis is "… the measurement of PFASs with an available analytical method for a specific set of substances and quantified against reference standards." EN 17681-1:2022, EN 17681-2 and Fpr EN ISO/FDIS 23702-2:2023 contain lists of PFAS that are recommended to be tested for textiles, leather and footwear. Grounded in the text outlined on page 9, it appears to be sufficient to test for the PFAS listed in standards like the mentioned ones. This is useful because it is not possible to test for several hundred single PFAS that are of no technical relevance in textiles, leather and footwear for consumers. It would also give all involved parties legal certainty and harmonises the testing approaches. If it is the intention of the EU that "the measurement of PFASs with an available analytical method for a specific set of substances" shall be performed it is required to state this very clearly, e.g. with the order to use applicable EN standards, in the restriction text and not as a comment in a proposal or later in a guidance document. The latter will lead to legal uncertainty and issues in the free movement of goods. It is highly recommended to initiate the development of standards of methods for PFAS testing in different matrices and for different product groups, ideally based on PFAS listed in EN 17681-1:2022. polymeric PFASs excluded from quantification: It is not defined in the restriction whether only polymers with a backbone that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (fluoropolymers), e.g. PTFE, count as polymeric PFASs or whether side-chain fluorinated polymers with hydrocarbon backbones also count as polymeric PFASs. A clear definition of polymeric PFASs in the restriction text needs to be provided in order to avoid confusion. It appears only meaningful that polymers with a backbone that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom count as polymeric PFASs since they cannot be analysed by targeted PFAS analysis whereas side-chain fluorinated polymers such as side-chain fluorinated polyacrylic polymers can often be degenerated and the released fluorinated side-chains, e.g. n:2 FTOH, can be analysed by targeted PFAS analysis. It does not appear logical that for the sum of targeted PFAS analysis a prior degradation of precursors can be optionally applied but not for the analysis for the single substances. This would mean two different test methods have to be applied. It appears to be more useful to apply the degradation step for testing of the single substances (i.) and the sum (ii.). In this case the side chains of side-chain fluorinated polymers will also be covered by the limit of 25 ppb resp. the suggested 1000 µg/kg.

		optionally with prior degradation of precursors: It is stated that the prior degradation is an optional step. What means optional? In which cases should a degradation be performed and in which one not. Clearly define the cases in the restriction and not only in the proposal or later in a guidance document. On page 9, it is outlined: "The concentration limit for the sum of PFASs (250 ppb) may be calculated from targeted PFAS analysis either analysed directly as sample or after chemical degradation of the sample material. The latter may include degradation products from e.g. side-chain fluorinated polymers." The use of may indicates an option and gives room for interpretation. How should market surveillance or third-party laboratories base any decision whether a product complies with the regulation on an option? The outcome of the degradation depends on the degradation method. Without referring to a particular test method different results are to be expected. We strongly recommend to add a phrase that the degradation shall be performed as outlined in the relevant EN standard. For example, CEN/TC 248/WG 26 "Textile and textile products - Test methods for analysis of EC restricted substances" is developing a standard that applies alkaline hydrolysis in order to degrade side-chain fluorinated polymers in order to test for compliance with the requirements of the POP regulation concerning PFOA related substances and the REACH regulation concerning C9-C14 PFCA related substances. Therefore, EN 17681-1:2022 is going to be revised. It is expected that the revised preliminary prEN 17681-1 will be published in the second half on 2023 and the final revised EN 17681-1 will be published in 2024. Labware or parts of labware consisting of PTFE Labware and parts of labware consist of PTFE. These labware or parts are required to analyse for several harmful substances. For instance, microwave digestion of samples for total metal analysis according to EN 16711-1:2016 which is done with aggressive acids, e.g. hydrofluoric acid, aqua regia, and oxidation agents such as hydrogen peroxide at temperatures above 200 °C and pressure above 200 bar cannot be done without PTFE containers.
		Answer to specific info request 1: TULAC
		Answer to specific info request 6: Labware or parts of labware consisting of PTFE Labware and parts of labware consist of PTFE. These labware or parts are required to analyse for several harmful substances. For instance, microwave

		digestion of samples for total metal analysis according to EN 16711-1:2016 which is done with aggressive acids, e.g. hydrofluoric acid, aqua regia, and oxidation agents such as hydrogen peroxide at temperatures above 200 °C and pressure above 200 bar cannot be done without PTFE containers.
		Answer to specific info request 10: CEN/TC 248/WG 26 “Textile and textile products - Test methods for analysis of EC restricted substances” is developing a standard that applies alkaline hydrolysis in order to degrade side-chain fluorinated polymers in order to test for compliance with the requirements of the POP regulation concerning PFOA related substances and the REACH regulation concerning C9-C14 PFCA related substances. Therefore, EN 17681-1:2022 is going to be revised. It is expected that the revised preliminary prEN 17681-1 will be published in the second half on 2023 and the final revised EN 17681-1 will be published in 2024. The joined working group of ISO/TC 216/WG 2 and CEN 309/WG 2 “Footwear and environmental aspects” will also start a standardisation project for a PFAS test method applying alkaline hydrolysis.

4131	**Date:** 2023/05/16 18:44 **Content:** Scope or restriction option analysis Hazard or exposure Baseline Information on alternatives Information on benefits Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** United Kingdom	**General Comments:** Scope or restriction option analysis: The generalisation of PFAS to include Fluoropolymers causes great concern. Our believe is that the use of PTFE components actual provides a reduction in risk to the environment, due to the properties it provides, high wear resistance, low friction values, excellent long term stability, high chemical resistance. A restriction/ban of its use would have a negative effect due to other materials having poorer performance. Many of the applications Fluoropolymers are utilised in are enhanced by PTFE and allow for greater efficiency's and more robust systems. Hazard or exposure: The PTFE supply chain that we are linked to have been aware of the PFAS issue for many years and have worked to remove this from there process. Many of our suppliers provide statements to confirm that PFAs, PFOA are no longer present in the PTFE polymer supplied (GFL, Dupont). Baseline: (See confidential attachment 1 for customer list). Yearly volumes 37000kg, contributing circa 25% of total turnover, into sectors such as Petrochem, Oil and Gas, Chemical processing plants, pharmaceutical, automotive, food and beverage industry. Our role in the supply chain is to provide components which are then utlised with the industries noted and components within equipment, processing line etc. The main focus is to improve sealablity and robust of all processes where a PTFE component is used. Product details, Slidebearing and skidway application, valve and pipeline connections, wear strips, bearing tapes, o-rings, Thrust washers, gland packings, body gaskets,

	Company name confidential: Yes **Attachment:** [redacted] **Privacy statement:** The data is propriety company information that could possible effect turnover if it was released. If you have specifics from the information you would like to release please contact us to request this and we will review it on a case by case basis.	chemical tanker seal, Chemical cargo ship seals, Labyrinth rings, diaphragms, rotary lip seals. Information on alternatives & Information on benefits: Research conducted to review alternatives to PTFE have highlighted the unique properties PTFE offers. It is almost totally chemically inert. It Has A Wide Temperature Range -250°C To + 250°C. It Has The Lowest Coefficient Of Any Solid Lubricant It is Non-Stick It is Self Lubricating It is easily machineable Moisture does not cause it to swell It does not degrade after exposure to long term direct sunlight Possesses excellent electrical properties as an insulator or as a conductor when compounded with desired fillers. See attachment 2 with comparison to Nylon 6. See attachment 3 for Biopolymer comparison LR2623. Beldam Crossley have supplied into the European space agency for components within the Ariane space craft/shuttle via Saffran. Again with Saffran PTFE is being supplied to contribute to greater engine efficiency within a hydrogen concept engine. Supply PTFE sealing rings used to seal the oil and gas pipelines throughout the world preventing pollution into our oceans etc.. Other socio economic analysis (SEA) issue: 15-20 employees are directly involved in the contributions to sales turnover linked to PTFE production.
		Answer to specific info request 1: Food contact materials and packaging - Industrial food production Medical devices - implantable medical devices Transport - Combustion engine systems, sealing applications Energy sector - wind energy, coal based power plants, nuclear power plants, PEM, Electrolysis technologies. Construction products - Bridge bearings, sealing and adhesives Lubricants - greases Petroleum and mining - lining of piping, sealsm sensors and cables
		Answer to specific info request 4:

		Current projects to use recycled PTFE as a percentage filler target 20% within or compounds PD53 (attachment 4)
		Answer to specific info request 6: OIl and Gas: Skidway application - transfer of oil and gas platforms (20000t upwards topsides, jackets etc.) from the dockside to the vessel the vessel into positions in the sea. PTFE is used as a bearing material between the skidshoes and the platform positioned in a track on the vessel. High load resistance material grades allows for heavier and heavier loadouts. We use 20000kg of material in this application per annum. and it contributes approx. 20% turnover. Link do demonstrate application https://www.youtube.com/watch?v=7eHjf7kU6eQ

4132	**Date:** 2023/05/17 02:59 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes **Attachment:** [redacted] **Privacy statement:** We want to keep the company name and use of PFAS in our chemical manufacturing confidential.	**General Comments:** Regulatory bans on PFAS used in equipment and materials for chemical manufacturing, for example fluoropolymers and refrigerant F-gas, for which there are no alternatives, would make manufacture of many chemicals impossible, and the impact on many applications would be serious. Consequently, PFAS used in equipment and materials for chemical manufacturing, for example fluoropolymers, F-gas should be excluded from the restriction of PFAS. **Answer to specific info request 1:** The chemical industry (chemical manufacturing) for which our comments are applied is not listed in the Annex XV restriction report (Table 9). PFAS used in equipment and materials for chemical manufacturing, for example fluoropolymers and refrigerant F-gas.

4133	**Date:** 2023/05/17 07:32 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Sun Fluoro System Co., Ltd. **Org. country:** Japan	**General Comments:** Sun Fluoro System Group provides Advanced Performance Vessel, which is lined with fluoropolymer, to the global market. Since our foundation on November 5, 1992, we have provided corrosion-resistant equipment, such as tanks, towers, containers, heat exchangers, and reaction vessels, to a variety of industries in the semiconductor, chemical, logistics, and environment. No other material offers chemical resistance and high purity for semiconductor applications that demands ultra-pure chemicals besides fluoropolymer. **Answer to specific info request 1:** In the semiconductors industry, various harsh chemicals are used. So, semiconductors apparatus requires chemical resistance and high purity. Fluoropolymers have strong chemical resistance and doesn't have any additives (plasticizers). **Answer to specific info request 5:** Sun Fluoro System Group usage APV (New PTFE): 250 ton/year, PFA: 50 ton/year Sun Fluoro System Group emission APV (New PTFE): 25 ton/year, PFA: 1 ton/year **Answer to specific info request 6:** a. Sun Fluoro System Group usage APV (New PTFE): 250 ton/year, PFA: 50 ton/year Sun Fluoro System Group emission APV (New PTFE): 25 ton/year, PFA: 1 ton/year b. High purity, Chemical resistance, Heat resistance c. 100 – 110 (SFS Gr Total) d., e., f. Not known g. It seems that only communist countries such as China and Russia will be able to keep producing PFASs, and they will enjoy the benefits in the various industries. **Answer to specific info request 7:** Because containers and tanks lined with Fluoropolymers (PFAS) don't contain any additives (plasticizers), the chemicals can be stored with high purity. In addition, compared with non-Fluoropolymers, Fluoropolymers (PFAS) have high chemical resistance, the apparatus lined with Fluoropolymers has long life time (more than 20 years).

4134	**Date:** 2023/05/17 08:19 **Content:** Scope or restriction option analysis Environmental emissions Baseline Information on alternatives	**General Comments:** Too many plastics are affected by the proposal, including common and less hazardous ones such as PVDF. A ban on PVDF will massively damage the chemical industry in Europe, since there are no alternative and durable plastics for a number of chemicals. PVDF fittings, pipes, pumps, gaskets etc. are not hazardous to the environment.

	Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Gramm Technik GmbH **Org. country:** Germany	If there is a ban, chemical plants will be built on other continents, the "problem" will only be postponed, jobs will be lost, chemicals will be bought from Europe.
4135	**Date:** 2023/05/17 11:32 **Content:** Scope or restriction option analysis Information on alternatives Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Industry or trade association **Org. name:** Japan Vending System Manufacturers Association (JVMA) **Org. country:** Japan **Attachment:**	**General Comments:** Environmental measures are being implemented worldwide to address global warming and achieve carbon neutrality. The vending machine industry itself is facing calls to transition to ultra-low global warming potential (GWP) refrigerants, ensure high energy efficiency, and maintain high safety standards. For vending machines that incorporate heat pumps for simultaneous heating and cooling to serve cold and hot beverages outdoors—vending machines which are expected to become increasingly popular in the EU—hydrofluoroolefins (HFOs) are the standout refrigerants. We do not consider hydrocarbon (HC) and carbon dioxide (CO2) refrigerants to be viable alternatives. Systems based on HC refrigerants indicated as alternatives contain limited charge amounts of the refrigerant, which makes them less energy efficient; likewise, the higher pressures required for CO2 refrigerants reduce energy efficiency. For these reasons, HFO vending machine refrigerants should be excluded from the proposed restrictions on perfluoroalkyl substances and polyfluoroalkyl substances (PFAS). As per the attachment in Section IV, the Japan Vending System Manufacturers Association (JVMA) supports the statement made by the Conference of Fluoro-Chemical Product Japan (FCJ), which questioned the proposed restrictions. **Answer to specific info request 1:** Vending machine refrigerants **Answer to specific info request 6:** We consider vending machine applications should be excluded as theses refrigerants are not viable alternatives.

	ref_4135_public.pdf [redacted] **Privacy statement:** Business Infomation	

4136	**Date:** 2023/05/17 11:51 **Content:** Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** VEGA Grieshaber KG **Org. country:** Germany **Attachment:** ref_4136_public.pdf	**General Comments:** VEGA sensors for level, point level and pressure measurement are used in all areas of industry and enable reliable control of processes. In many applications, the sensors are used in safety-critical applications and make an indispensable contribution to preventing hazards to people, plants and the environment. At the moment no alternatives are available that are equivalent or superior to the used materials. Furthermore, we are not aware of any equivalent alternative materials currently under development. Development, Certification and regulatory approvals are not being achieved within a 5-year derogation period. Therefore a derogation of 18 months + 12 years is necessary. Therefore, we also support the "Statement on the REACH restriction proposal of PFASs" from VCI dated April 21st 2023 completly.
		Answer to specific info request 6: a. Substance PVDF >25 tons p.a. Substance PTFE >15 tons p.a. b. True air microwave level measuring sensor • Water resistance, very low water absorption • Gliding performance, less friction, low abrasion • Dielectric constant • Radiation resistance • Chemical resistance • Flame / burn characteristics • Temperature resistance at high and low temperature • UV radiation resistance • Material strength even at very high and low temperatures Guided microwave level measuring sensor • Dielectric constant • Temperature resistance at high and low temperature • Chemical resistance • Water resistance, very low water absorption • Radiation resistance • Flame / burn characteristics • UV radiation resistance • Material strength even at very high and low temperatures Pressure measuring sensor • Water resistance, very low water absorption • Gliding performance, less friction, low abrasion • UV radiation resistance • Material strength even at very high and low temperatures • Chemical resistance • Temperature resistance • Flame / burn characteristics Point level sensor • Temperature resistance at high temperatures • Gliding performance, less friction, low abrasion • Chemical resistance • Flexibility •

		Capacitive level sensor • Water resistance, very low water absorption • Gliding performance, less friction, low abrasion • UV radiation resistance • Temperature resistance • Dielectric constant • Chemical resistance • Material strength even at high and low temperatures • Flame / burn characteristics • Conductive level sensor • Water resistance, very low water absorption • Chemical resistance • Electrical isolation • Gliding performance, less friction, low abrasion • Dielectric constant • Temperature resistance Radiometric level, density and flow sensor • Temperature resistance at high temperatures • Gliding performance, less friction, low abrasion • Water resistance, very low water absorption • Gliding performance, less friction, low abrasion Housing and probe material for sensors: ☐ FPs provide a wide temperature resistance range from very low (-50°C) to very high temperature (250°C). Also, they provide an excellent chemical resistance for wide range of application in e.g. Chemical Industry, Water/Waste Water Industry. ☐ Often, the used materials require material certificates and approvals for e.g. FDA, Water/Waste Water Industry, Pharma/Food-Industry,…. FPs do provide most of these approvals. ☐ FPs do provide fire defence/protection as well as options for outdoor. ☐ Therefore FPs are used as standard materials for sensors in industrial process measurement as well as for process automation and factory automation. Level and Pressure Sensors using microwave principles or capacitive principle (e.g. VEGAPULS, VEGAPOINT, VEGACAL) ☐ FPs are used due to their excellent microwave characteristics. They provide a low dielectric constant and a low loss over a wide range of environmental conditions. ☐ For VEGAPULS, a level measurement instruments using RADAR principle in the frequency range between 5 and 80GHz, FPs are used as standard materials for the interface between the sensor and the container or tank in e.g. chemical or pharma industry. General use ☐ FPs are used due to their friction reducing function for joints or threads. ☐ FPs are used because they provide excellent insulating / electrical characteristics for e.g. high voltage isolation at main supplies and in cables. c. Sc. Sensors for the process and factory automation are being used in numerous industries every time a (process) pressure or a (tank) level has to be measured. With millions of sold measuring devices several thousand companies could be affected within the EU. d. Particularly in radar technology, plastics are needed that cause the lowest possible signal attenuation for microwave signals; this property is particularly given by PTFE. No other plastic is as suitable for radar applications as PTFE. The use of other plastics leads to considerable functional limitations, so that media such as hydrocarbons or solvents can no longer be measured, or only with great restrictions. e. Various research have taken place to identify FP-free alternative products since 2020. We have not been able to find materials that can directly replace FPs without limits in function (device performance) and in application range. There are materials without FPs identified (e.g. ceramics, PEEK, PP, PPSU, PEI) that could replace some of the FPs. But this would end in limited usage for our customers as well as of the higher production and market price for sensors. f. i. At company level this could be roughly estimated with 500 million Euros. ii. +10 years iii. Potential alternative Products or product groups examined

		Technical feasibility (performance, technical characteristics, etc.) Economic feasibility (cheaper, more expensive, reason)? Steel & other metals X Not usable - High nickel alloys X Not usable - Polypropylene X Limited use due limited to temperature range and chemical and environmental characteristic like e.g. UV radiation - PVC - Evaporation of chlorine - Glass / Ceramics / Mica X Limited application range (chemical resistance for glass) Economical reason (much more expensive) Polyether sulphone - - - Polyimide X Not processable for injection moulding - EPDM rubber X Limited chemical and temperature resistance - Nitrile rubber (NBR) X Limited chemical and temperature resistance - Hydrogenated NBR - - - Acrylic rubber - - - Ethylene-acrylic (AEM) rubber - - - PEEK X not resistant to UV radiation - Polycarbonate X Poorer chemical resistance to solvents - Polyamid X Higher water absorption and thus variations in dimensional stability and material properties - Other (please describe) - - - iv. At the moment no alternatives are available that are equivalent or superior to the used materials. Furthermore, we are not aware of any equivalent alternative materials currently under development. g. Currently, 100% of the core technology is produced in Germany. The two production sites in the USA and India are purely assembly sites. This means that the entire production chain is collapsing. The devices with FPs amount to 71% of the total turnover. Total turnover was around 600 million in 2022. 2000 employees are affected. It is possible to build up the production facilities abroad within 5 years. By shifting the vertical range of manufacture abroad and thus the value added, additional tax burdens are incurred in Germany.

4137	**Date:** 2023/05/17 12:39 **Content:** Scope or restriction option analysis Information on benefits Request for exemption **Type:** Individual **Country:** United Kingdom	**General Comments:** FLUOROPOLYMERS – POLYMERS OF LOW CONCERN According to OECD criteria, fluoropolymers are polymers of low concern. Most of them are also suited and qualified for medical and food contact applications. They are: ☐ Non-toxic, ☐ Non-bioaccumulative, ☐ Non-mobile, ☐ Insoluble in water and organic fluids, ☐ Stable thermally, chemically and biologically, ☐ Durable. PTFE gives more to humankind that the negatives it takes away.
		Answer to specific info request 7:

		There is no known alternative to PTFE lined hoses. Infact the life of a PTFE hose can be tenfold of its nearest competitor so its environmental impact is actually less than other alternatives over the lifetime of the application.

4138	**Date:** 2023/05/17 13:23 **Content:** Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Metadynea Austria GmbH **Org. country:** Austria	**Answer to specific info request 8:** • We purchase around 7,000 seals per year, mainly flat seals • Of these, around 80% fall under PFAS • There are also many other products where PTFE molded parts are used (fittings, mechanical seals,...). These are definitely the more critical applications where a full replacement with another material is currently difficult to imagine. • A possible replacement product would have far-reaching chem. Durability, temperature resistance, good resilience and very good sliding properties. • Derived from this, due to the excellent properties as a sealing material, there are in practice low leakage rates and consequently low fugitive emissions. This must be taken into account in any case in connection with sensitive substances. • A ban on use (= replacement of existing, intact seals, fittings, etc.) would be an economic catastrophe and not manageable for industry.

4139	**Date:** 2023/05/17 14:12 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Academic institution **Org. name:** University Leipzig, Chemistry & Mineralogy	**General Comments:** In a joint project with industry partners we have developed over 5 years a new absorber molecule containing one CF3-SO2- Group with a molecular weight of the whole molecule of 1232 g/mol. Product is intended to be used in electronic data storage systems with a total volume of 500 - 800 kg per annum. New product is ready for market launch during the course of 2024. Within the 5 year development programme we have not been able to find a compound with similar properties but w/o the CF3 Group.
		Answer to specific info request 2: The maximum use of the compound will not exceed 800 kg per annum, the component with a CF3-content of 5,5 %. Compound is embeded in a polymer layer on a Aluminium substrate. After use the product is recycled in the normal Aluminium recycling process. The molecular weight of the compound is too high to support any emission from the polymer substrate.
		Answer to specific info request 4:

	Org. country: Germany **Attachment:** [redacted]	Compound is part of a data carrier coating on a aluminium substrate and is fully mineralized in the normal aluminium recycling process. **Answer to specific info request 5:** as specified earlier - the maximum use within Europe would be in the magnitude of 800 kg / 0,8 tons per annum. **Answer to specific info request 6:** Compound is part and single output of a research programme. More than 30 substructures w/o CF3 group have been tested but do not show the required color change after laser imaging. **Answer to specific info request 7:** In the event, that the compound can not be used in the market, the data storage systems will have to continue to undergo chemical development, hence the use of the compound would enable a reduction of process chemicals. **Answer to specific info request 8:** no other uses **Answer to specific info request 10:** Compound can be measured by typical HPLC methods

4141	**Date:** 2023/05/17 17:13 **Content:** Scope or restriction option analysis Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Schreiner Group GmbH & Co. KG **Org. country:** Germany **Attachment:**	**Answer to specific info request 1:** Technical textiles We refer to our initial submission of 22 March 2023 (Ref. 3834 according to the RCOM document available on the ECHA webpage). For further communication the following reference number has been provided: b7efc58e-c919-4083-8360-6e7ec5195d29 We would like to refer to the aforementioned reference number and provide our detailed submission as follows.

	ref_4141_public.pdf [redacted] **Privacy statement:** The document contains relevant confidential technical and business data. Public access to the document would negatively impact our business interests.	

4142	**Date:** 2023/05/17 17:20 **Content:** Information on benefits Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** FiberFin Inc. **Org. country:** United States of America	**Answer to specific info request 1:** Plastic Optical Fiber (POF) is utilized in various products across different industries. Here is a list of some common products that make use of POF: Communication Devices: Digital audio cables Home theater systems Soundbars and speakers Gaming peripherals (headsets, controllers) Automotive Applications: Automotive lighting systems (LEDs, interior and exterior lighting) In-vehicle networking and communication systems Infotainment systems Advanced driver assistance systems (ADAS) Industrial and Automation: Industrial networking and communication systems Robotics and automation equipment Machine vision systems Industrial sensors and monitoring devices Medical Applications: Endoscopy and surgical instruments Medical imaging and diagnostics equipment Patient monitoring devices Medical sensor systems Consumer Electronics: Fiber optic lighting and decorative applications Fiber optic displays and signage Consumer electronic devices with optical connections (audio/video equipment) Aerospace and Defense: Avionics systems Communication systems for aircraft and military vehicles Military-grade networking and data transmission Data Centers and Telecommunications: Local Area Networks (LANs) Fiber-to-the-Home (FTTH) broadband connections Optical network equipment Data center infrastructure and high-speed interconnects Energy and Lighting: Fiber optic lighting systems (architectural, commercial, and residential) Light guides and light transmission solutions LED lighting applications This is not an exhaustive list, as the use of POF continues to expand into new applications and industries. The versatility, cost-effectiveness, and reliability of POF make it a popular choice for various products that require efficient data transmission and optical connectivity. **Answer to specific info request 6:**

		FiberFin Inc. is company that solely focuses on the manufacturing, distribution, and support of the the Plastic optical fiber (or also called polymer optical fiber). a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use. i. FiberFin consumes hundreds of thousands of meters of plastic optical fiber annually and it's the primary raw material of our business. b. The key functionalities provided by PFAS for the relevant use. i. Medical: Plastic Optical Fiber (POF) holds significance in the medical industry for several reasons: a. Medical Instrumentation: POF is utilized in medical instrumentation for various applications, such as endoscopy, surgical robotics, and diagnostic devices. Its lightweight and flexible nature make it suitable for transmitting light signals used in imaging, illumination, and sensing within medical equipment. b. Minimally Invasive Procedures: POF enables the development of minimally invasive procedures by providing flexible light guides for devices like catheters and endoscopes. These optical fibers can be inserted into the body to deliver light and transmit images, enabling healthcare professionals to perform diagnostic or therapeutic procedures with reduced invasiveness. c. Biomedical Sensing: POF can be employed in medical sensors for monitoring vital signs, such as blood oxygen levels, pulse rate, or glucose levels. The fiber's ability to transmit light signals without interference or electrical noise makes it suitable for reliable and accurate sensing applications. d. Patient Monitoring and Communication: POF can be utilized in wearable devices for patient monitoring and communication. It can transmit data from sensors attached to the body to external monitoring systems, providing continuous monitoring of patient parameters. Additionally, POF can facilitate communication between medical devices and external systems, enhancing the efficiency of healthcare operations. e. Safety and Compatibility: POF is non-conductive, immune to electromagnetic interference, and poses no electrical hazard, making it safe for use in medical environments. Moreover, its compatibility with sterilization processes, such as autoclaving, makes it suitable for applications requiring stringent hygiene standards. f. Overall, Plastic Optical Fiber plays a crucial role in the medical industry by enabling advanced medical instrumentation, facilitating minimally invasive procedures, supporting biomedical sensing, and enhancing patient monitoring and communication. Its unique characteristics make it a valuable tool in improving healthcare delivery, diagnostics, and patient care. ii. Agricultural a. FiberFin employes POF for numerous agricultural products for some of the largest implement companies and also for the irrigation of crops. POF plays a critical role in the effectiveness of the overall products. iii. Safety: a. POF offers enhanced safety in robotic systems. Unlike copper cables, POF does not conduct electricity, reducing the risk of electrical hazards. This is particularly important in situations where robots interact with humans or operate in sensitive environments. The non-conductive nature of POF provides an additional layer of safety in robotic applications. iv. EMI Immunity: a. POF is immune to electromagnetic interference (EMI) and radio frequency interference (RFI). In robotic environments where various electrical devices and motors are present, the immunity of POF to EMI ensures stable and accurate data transmission. This makes POF an ideal choice for critical applications

		where signal integrity is paramount. v. Data Transmission: a. POF enables high-speed and reliable data transmission in robotics. It can carry signals such as control commands, sensor data, and video feeds, allowing robots to efficiently communicate and respond to their environment. The fast data transmission capabilities of POF contribute to real-time decision-making, enhancing the overall performance and responsiveness of robotic systems. c. The number of companies in the sector estimated to be affected by the restriction. i. FiberFin currently has over 2,000 customers utilizing POF in their application. As POF is the only media we utilize this would directly impact all these customers. d. 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. i. There are no alternative materials to manufacture POF and the only other replacements are silica fiber and copper cable which are not the equivalent and cannot by used in a medical application. e. 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. i. The manufacturers of the raw fiber have informed FiberFin there are no alternatives for this chemical to make POF. The production of POF would cease to exist if the chemical was banned. f. For cases in which substitution is technically and economically feasible but more time is required to substitute: i. There are no substitutions available now or in the feasible future. g. 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. i. As a US based company we cannot comment on the total value of the EU sales of POF but we will be able to comment and state that EU is a critical market for FiberFin and the POF industry in general. Many companies use POF for a numerous applications and products so we feel that the job and economic losses would be significant if POF was no longer available.
		Answer to specific info request 8: If Plastic Optical Fiber (POF) were no longer available FiberFin would cease its operations given that our core business revolves around POF. In general if POF was no longer there would be several issues and challenges that could arise in various industries and applications. Here are some potential consequences: Limited Data Transmission Options: POF provides a cost-effective and reliable solution for high-speed data transmission. Without POF, industries relying on its benefits may face limited options for efficient and affordable data transmission. This can impact areas such as

		telecommunications, automotive networking, industrial automation, and medical diagnostics. Increased Reliance on Traditional Copper Cables: In the absence of POF, industries may have to rely more heavily on traditional copper cables for data transmission. Copper cables have limitations such as limited bandwidth, susceptibility to electromagnetic interference (EMI), and greater signal loss over longer distances. This could lead to decreased performance, slower data speeds, and potential reliability issues in critical applications. Reduced Flexibility and Maneuverability: POF's lightweight and flexibility are advantageous in applications that require routing through tight spaces or around moving parts, such as robotic systems. The unavailability of POF could limit the design and implementation of flexible and agile systems, impacting industries such as robotics, industrial automation, and medical devices. Compromised Immunity to Electromagnetic Interference: POF is immune to EMI and radio frequency interference (RFI). Without POF, industries may face challenges in maintaining reliable and interference-free data transmission, particularly in environments with high EMI/RFI levels. This can result in decreased signal quality, potential data corruption, and increased susceptibility to external noise sources. Higher Costs and Complex Installations: POF is known for its cost-effectiveness and ease of installation due to its simpler manufacturing process and compatibility with existing infrastructure. The unavailability of POF could lead to higher costs associated with alternative optical fiber solutions, as well as more complex installation processes. This can impact industries such as telecommunications, data centers, and consumer electronics. Potential Performance Limitations: POF offers advantages such as low attenuation, low dispersion, and wide acceptance angles. Alternative optical fiber solutions may not provide the same level of performance or may have limitations in terms of distance, bandwidth, or signal quality. This could result in compromised system performance and reduced capabilities in various applications. Slower Technological Advancements: The absence of POF may slow down the pace of technological advancements in industries that heavily rely on fiber optic solutions. POF has been a driving force behind innovations in areas such as high-speed data transmission, medical imaging, and industrial automation. Without POF, research and development efforts in these fields may face challenges in finding suitable alternatives and making progress. It's important to note that these issues are hypothetical and based on the assumption of POF no longer being available. However, they highlight the potential impact of losing the benefits and capabilities that POF currently offers to industries and applications.

4143	**Date:** 2023/05/17 18:48 **Content:** Transitional period Request for exemption	**Answer to specific info request 6:** PTFE used in internally lubricated engineering thermoplastic (ETP) compounds for drinking water and water management applications.

	Type: BehalfOfAnOrganisation **Org. type:** Company **Org. name:** SHPP B.V. **Org. country:** Netherlands **Attachment:** ref_4143_public.pdf [redacted] **Privacy statement:** Disclosure would undermine the protection of commercial interests	

4144	**Date:** 2023/05/17 19:51 **Content:** Scope or restriction option analysis Information on alternatives Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Industry or trade association **Org. name:**	**General Comments:** Electrolysers and fuel cell applications are the hydrogen industry's fundamental technologies. Other process technologies across the value chain are also essential for the deployment of the hydrogen economy (compression, purification, liquefaction storage components). Both electrolysers and fuel cells and those other processes are heavily reliant on fluoropolymers (considered a PFAS subtype). No alternative is foreseen today or in the near future to substitute these highly specialised materials, crucial for the EU transition towards climate neutrality. These fluoropolymers are produced under responsible manufacturing conditions and used in a highly controlled industrial environment, where their emissions are negligible (see answer to Q2), and, due to their high initial price, their reusability and recyclability are actively investigated and inherently encouraged. The restriction proposal's approach to group together all fluoropolymers with other PFAS types must be revisited. Henry (2018) (note 1) and Korzeniowski (2022) (note 2) demonstrated that most fluoropolymers meet the OECD criteria to be defined as 'polymers of low concern'. They verifiably do not

	Hydrogen Europe **Org. country:** Belgium **Attachment:** ref_4144_public.pdf [redacted] **Privacy statement:** Confidentiality is required for the below information as the data was provided to the Hydrogen Europe secretariat in a confidential manner, and it would harm industrial competitiveness to disclose such data regarding testing, R&D and innovation.	pose a risk to human health or the environment as they are not water soluble, toxic and bioavailable. In addition, fluoropolymers uses in the hydrogen value chain are restricted to highly controlled industrial environments, where contact with workers or consumers is demonstrably limited and strictly supervised (note 3). Therefore, regulatory action should focus on tackling any potential PFAS emissions at all life-stages (manufacturing, use and end-of-life) and not on banning these essential, high-performing and low-concern products. Fluoropolymer production and use shall therefore be exempted from the U-PFAS restriction. For exempted uses, legislators should set up a framework incentivising a) best practices for the manufacturing, use and end-of-life stages of fluoropolymers, implementing circular economy practices across value chains (closed circle with take-back system implementation and recycling/reuse at disposal stage) in the short and medium term, and b) research into finding alternative products (whether fluorinated or not) that could at minimum reach or ideally even surpass the same KPIs as currently used fluoropolymers offer (considering performance, quality, durability, efficiency, availability and economic viability, on top of overall lifecycle risk reduction) in the medium to long term. A PFAS ban without exempting fluoropolymers would have destructive effects on the industry's €30-billion worth of investment in a decade (only including electrolysers and fuel cells). For instance, such a ban would push the fuel cell technology back to approximately TRL 2 in terms of power density and durability (note 4). It would jeopardise up to 200,000 direct and over 260,000 indirect jobs within 10 years in a market with a potential value of €820 billion employing 5.4 million jobs by 2050 (note 5). Although rightly acknowledging the use of fluoropolymers in the hydrogen sector, the draft restriction proposal used outdated data. In point (i) of E.2.12.1 of the proposal, the drafters used 2020-2021 data, referring to 40 GW of target electrolyser capacity in the EU, which is today a goal of 140 GW of capacity by 2030 according to the REPowerEU plan. Regarding socio-economic considerations, this would mean that contrary to the low amounts represented in the restriction proposal, taking the REPowerEU Plan as basis for future investment, a general PFAS ban would jeopardise around €1.8bln accumulated investment by 2024 in electrolysers only. Since PEM, alkaline and other electrolysers are indispensable for large scale renewable energy source (RES) integration with the power grid, and are key in sector coupling, a ban would not only restrict the hydrogen market, but could also negatively affect the deployment of needed RES capacities on the EU market (note 6). In a ten-year view, the ban would jeopardise investment worth €18.75bln in electrolysers only (based on REPowerEU). In the mid-term, the general PFAS ban would also severely impact applications in the military (note 7) and mobility (maritime, aviation, road and rail). With expected fleet numbers, the fuel

		cells systems alone in all those vehicles are estimated to be around €18.7bln, with an additional €2bln for refuelling stations. In total, in a 10-year timeframe the proposed general PFAS ban would put at risk a total investment value in the clean hydrogen sector of €26-36bln. Additionally, it would put 147-203 thousand jobs, and an extra 263-282 thousand indirect jobs at risk. One Hydrogen Europe Member claimed that for its company, by 2025 fluoropolymer membrane-based fuel cell stack production would mean an annual €0.5 billion in turnover and around 500 jobs for the company, which would all be lost with a blanket ban on fluoropolymers. On top of the risk of missing EU climate targets, a PFAS ban in the EU would lead to a global market distortion, as hydrogen technology producers outside the EU could gain significant competitive advantage by not being covered by this restriction (note 8). In Table E.134 the proposal shows an imprecise understanding of the hydrogen sector and value chain by only including essential components under "PEM fuel cell" applications, such as Membrane electrode assemblies or Gas diffusion layers, and not under PEM electrolysers. These are critical for both applications and there is no reason why both technologies – which consist in the same but reversed process – be handled differently in this context. Another consequence of this imprecision is the consideration of membrane technologies and alternatives under PEM electrolyser and fuel cell gaskets. This puzzling categorisation of technologies and their components is a critical issue that may have caused the drafters to only propose a time-limited derogation to PEM fuel cell applications. In particular, fluoropolymer membrane technology is essential for the alkaline electrolyser value chain too, since the liquid electrolyte (KOH) required for its process must be manufactured by electrolysis with fluoropolymer membrane as the Best Available Technique, since the alternative would be via mercury or asbestos (both of which are highly toxic and banned). There is no argument raised for not including PEM electrolysers or other types of fuel cell and electrolysis technologies (like alkaline, solid oxide electrolyte cell or anion exchange membrane) under the derogations. Those technologies are as unviable without fluoropolymer-based components as PEM fuel cells and they are as essential for the EU's decarbonisation goals as PEM fuel cells are. After having provided ample documentation (e.g. in the Call for Evidence 2021 Restriction PFAS) during the drafting period on all mentioned technologies (beyond PEM fuel cells) and on the essentiality of fluoropolymers for their functioning, Hydrogen Europe calls for not only PEM fuel cells to be included in the restriction proposal's list of exemptions. The proposal omits the use of fluoropolymers in sealings, coating, valves, filtration and lining components all along the hydrogen infrastructure, not least in grids and storage units (cf answer to Q8). Fluoropolymers are also key in CCUS technologies (note 9) and hydrogen end use applications, from mobility to industrial off-takers, such as ammonia or steel production, meaning that the sectoral spillovers are substantial; the ban of fluoropolymers in one sector can still jeopardise others, including the hydrogen industry (note 10). Additionally, it is necessary to clarify the position of fluorinated materials required to produce

		fluoropolymers, which are today critical for the continued use of fluoropolymers in the hydrogen sector. It was mentioned by the ECHA during the April 5 Q&A session that a derogation of a use brings about the same derogation for the entire upstream value chain of that use (including the use of monomers and polymerisation aids in the case of fluoropolymers). This should be clarified in the restriction dossier for legal certainty. It is necessary to note that even if the upstream value chain of a fluoropolymer used in a derogated case is also derogated from the restriction, and therefore could continue production; the business case of those plants would still be severely impacted. Also, clarity is needed on the fact that spare parts are also derogated and therefore allowing for continued repair and maintenance, as the competitiveness of hydrogen technologies would decrease rapidly if they cannot be utilised for their intended operation time (note 11). Considering the low risk profile of fluoropolymers, the lack of alternatives in a particularly demanding environment, and potential socio-economic impacts, we hold that fluoropolymer production and use should therefore be exempted from the overall PFAS restriction.
		Answer to specific info request 1: Energy sector
		Answer to specific info request 2: a. During the manufacturing of fluoropolymers, PFAS emissions are strictly controlled at production sites. Manufacturing companies must already comply with rigorous environmental standards. It is important to note that, as it is implied in the general comments of this section, and identified in the restriction proposal, the volumes of fluoropolymers used in the hydrogen sector is dwarfed by PFAS substances used in other sectors, where the use of these substances may not be essential (cf. answer to Q5 on PFAS tonnage in the hydrogen sector). On potential emissions during manufacturing of fluoropolymers, we would like to point you to confidential note 1 and to inputs provided to this ECHA public consultation by certain Hydrogen Europe Members, such as Gujarat Fluorochemicals, among others. During the use of fluoropolymer-containing components in electrolyser and fuel cell applications, there are negligible PFAS emissions in the water or in surrounding equipment. Nevertheless, a number of Hydrogen Europe Member companies are currently undertaking a data gathering exercise that will provide robust, sufficient data supporting the claim that the amount of PFAS emissions in the water or in the surrounding equipment is negligible. We aim at providing findings in a second submission to this ECHA public consultation in September, before the ECHA deadline. On the question of emissions during the end-of-life phase in hydrogen industrial applications, please consult our answer to question 2(b) of this questionnaire. b. End of life incineration, including exhaust gas treatment in a safe and controlled way is the current standard operation for fluoropolymer membranes used in all types of electrolysers

		and fuel cells. All exhaust gases are treated at the highest standards and in line with EU and local legislation, and there is no indication that PFAS remains after incineration under the conditions used (note 12). Still, there is no EU-level legislation on PFAS emissions regarding incineration. A mutual standard on this is a prerequisite for future legislation. Industrial actors had already initiated alignment to work out a proposal on this topic; addressing potential emissions of fluoropolymers at end of life should be a regulatory priority, as opposed to a complete ban on the materials. Taking fuel cells in mobility applications as an example, at end-of-life stage, vehicles containing fuel cells are dismantled, and the modules are removed, after which the stack itself is dismantled to collect the cells. The cells are then -as described above- incinerated to recycle the platinum group metals (PGMs), while the ionomers are fully destroyed with hydrogen fluoride (HF) emissions. The same is also done with fluoropolymers from other applications, such as PEM electrolysis. The resulting fluor-containing emissions are then captured and treated, whilst the results are also measured against rigorous environmental standards. As noted above, there is data available for this process for PTFE, which has been measured under controlled conditions (note 12). However, to date there is no systematic data collection available on potential emissions (e.g., from fluoroionomers) – hence the value of exploring the potential of a monitoring, reporting and verification (MRV) system. It should be made clear that, for fluoropolymers, the way forward is for recycling to progressively replace abovementioned incineration practices. Also, due to overwhelming economic imperative, it is obvious that PEM fuel cells will be increasingly recycled, especially when significant volumes at end of life are reached. In fact, it is possible that close to 100% of platinum recyclability can be reached (Note 13). In addition, you can see in confidential note 2 an example of recycling, where 100% of membrane is separated from Critical Raw Materials, which means that return of membrane material and efficient separation is viable. Since the applications would be relatively undiversified, take-back systems are highly realistic to enable this recycling. Certain Members of Hydrogen Europe have already started to systematically take back end-of-life products and some argue that in just 5 years there will be no landfilling of PFAS containing components from fuel cells and electrolysers. Besides incineration, there are research tracks underway aimed at enabling regaining the ionomers. While it is possible to separate the precious metals from the membrane, right now the ionomer is altered so far that it cannot be used again in another fuel cell. Currently there are no known processes to “repair” the material back to sufficiently high grade, which would be necessary for fuel cell applications. Additionally, the risk of ionomer diversity in the different PEM fuel cell products raises the issue of having to develop slight variations of recycling technologies. A value chain for recycled end of life materials from high-demanding applications to raw materials for lower-demanding applications needs to be established. The tabled restriction would prevent this, as it would limit the already low volumes. Therefore, a robust recycling process requires both development time and sufficient volume of end-of-life components and applications where the regained materials can be used in. PEM electrolysers

		and PEM fuel cells rest on the same scientific basis and are developed as similar technologies. Although they are different products, this was not acknowledged in the restriction proposal. Moreover, synergies could be developed, whereby the recycled ionomer materials from fuel cells might be utilised in water electrolyser technologies. However, these processes would have to be developed, which requires legal certainty for the industry to carry out continued use and development with fluoropolymer components. Unfortunately, the recycling of both PGMs and fluoropolymers for both fuel cells and electrolyser systems could be jeopardised by the PFAS restriction proposal, as there would be no more end-market. As a nascent market, fuel cell vehicles have not yet reached the necessary volume at end of life. This is the main reason for the lack of development of a recycling ecosystem. It should be noted that by 2030, even assuming a 10% waste along the value chain, the accumulated volumes would already be significant even with a small number of devices having reached end of life. Nevertheless, investment has been committed to research on the topic, for example the HyTechCycling project (note 14) in addition to one Hydrogen Europe Member investing €500 thousand. Other Members are also putting in additional capacities into projects that scale up the entire end-of-life process (e.g. in the H2Giga project – note 15). The US Dept. of Energy is planning to invest $50M into recycling research for PEM fuel cell and electrolysis between 2023-2027, with additional funding planned for projects scaling up ionomer recapturing (note 16). In addition, the Dept. of Energy collaborated with industrial partners, the American Institute of Chemical engineers, universities and national laboratories to develop technology relevant to circularity, recycling in the hydrogen economy, and to address end of life and critical supply chain challenges. The Clean Hydrogen Partnership also financed cooperation on developing projects tacking the recycling of end-of-life hydrogen technologies. For instance, the BEST4Hy project (2021-2023) (note 17), with a €1.5 million is aiming to demonstrate high recovery yield of ionomers (80%), and the re-manufacturing of new cells/stacks with at least 70% of ionomer and 95% of platinum in PEM stacks. It could apply life-cycle assessment (LCA) and life-cycle costing (LCC) methodologies to the whole life cycle of electrolysis and fuel cell technologies, which could bring fact-based information on potential environmental impact of these technologies' end-of-life. Additional efforts by close cooperation of research institutes and industry are invested in the currently running BReCycle project, with a total funding of €1.2 million (note 18). Further, sealing elements out of reciprocating compressors for Hydrogen applications of PTFE are produced from semi-finished bushings. Bushings are optimized in diameter and height to minimize waste and safe costs as good as possible. Nevertheless, approximately 70 % of the used material is PTFE (because of filler components like graphite, glass fibres and others). Approximately 30 % of the machined bushings are waste during the machining process at the production of the sealing elements. This waste can be recycled, and such a recycling process has already been established in this industrial sector. Similarly, at end of life of such sealing devices,

			although incineration is the current standard operation, recycling of these devices is possible, as has been proven by one of Hydrogen Europe's members (confidential note 3).
			Answer to specific info request 3: Today, there is an overwhelming economic imperative to recover PEM stacks (both fuel cells and electrolysers) at the end of the life cycle in order to reclaim and recycle the expensive PGM (Platinum Group Metals) catalysts contained within the membrane/electrode assemblies, as well as the fluorine. Recycling processes enable the recovery of the fluorine contained in the ionomer, for instance in the form of calcium fluoride, made of fluorspar, or fluorite (which is on the EU's 2020 critical raw materials list). Calcium fluoride can then be used as a raw material input for further production of fluorine-containing material. Therefore, it is financially discouraged that associated fluoropolymer components will enter the general waste stream. Furthermore, there is strong promise that the fluoropolymer ionomers can be recovered and reused in the polymer form at the end of its lifecycle as demonstrated in the UK Research and Innovation (UKRI) project Frankenstack (note 19) and by Carmo et al. 2019 in PEM catalyst separation, recovery and recycling (note 20), which is illustrated in confidential note 2 In addition, several patents exist entailing methods for recovering and recycling catalyst coated membranes (CCMs) through dissolving the membranes and separating the components (note 21). Recent peer-reviewed studies carried out by Aleksandrov (2019) on the disposal of end-of-life PTFE have shown incineration to be an appropriate way to dispose of the fluoropolymer too, with no environmental concern (note 22). The said study found that the combustion of PTFE under typical waste incineration conditions (municipal level) and using Best Available Techniques (BAT) does not degrade into the identified PFAS of environmental concern. It also showed that in standard municipal waste incineration conditions, PTFE is essentially transformed to carbon dioxide and hydrofluoric acid. They thus concluded that the municipal incineration of PTFE should therefore be considered an acceptable form of waste treatment (note 22). It should be noted, additionally, that the Dutch Institute for Public Health and Environment (RIVM) drew slightly fewer concrete conclusions, mentioning that, although it can be assumed that the polymer molecules are destroyed with the gasification process, this does not provide enough information on the kind and degree of by-products formed and on the rate of mineralisation (Note 2). Additional research would therefore be needed on the topic to fill in those gaps. Regarding the sealing devices in the hydrogen ecosystem, including in reciprocated compressor systems, it can be concluded that with an established PTFE recycling process, the incineration of PTFE-based products will not be needed. It is therefore visible that in the wider hydrogen industry recycling is the preferred way forward, not only based on sustainability but also on efficiency and on economic considerations.
			Answer to specific info request 4:

		Recycling of PTFE-based sealing materials for Hydrogen compressor systems is already established. If materials are collected grade by grade, the recycling process can be enlarged to cover nearly 100 % of all waste inhouse. Professional grinding companies are already on the market that allow the recycling of these perfluorinated polymers. A Process Technology is providing efficient grinding equipment for the recycling process and Dressler Group is providing grinding service for their customers (confidential note 4. Basically, the recycling of perfluorinated polymers is split into 4 steps: 1) Collecting grade-specific waste 2) Grinding process with milling particles down to about 20 – 30 microns 3) Mixing grinded material with new material (Normal powder mixing process) 4) Producing new semi-finished products from new mixture including recycling material Recycling costs are roughly 10€ per kilogram which is nearly equal to the costs of the new material. This means, that it is feasible from a financial point of view
		Answer to specific info request 5: Before all, it should be noted that it is extremely difficult to calculate the amount of fluoropolymer needed by the hydrogen sector. Therefore, it needs to be mentioned that the below are estimations only for PEM fuel cell and water electrolysis and that those are only based on the current state of the technology, and do not account for possible efficiency improvements. This innovation could be substantial and should not be ignored, particularly if membrane development history gives an accurate indication of potential future performance. To illustrate, the PEM industry has been developing for over 20 years and in that time has reduced the thickness of membranes dramatically. Starting with Nafion® 117 from Chemours, considered an industry standard at 175 μm thick, this was replaced with Nafion® 115 at 125 μm thick. Developments are still underway to reduce membrane thickness even further. Proton exchange membranes' thickness for fuel cells used in automotive applications is typically under 20 μm, whereas thickness is usually around 100 μm for water electrolyser membranes. In total, a 60-kW PEM fuel cell stack with a total weight of 28.5 kg contains the following amounts of fluorinated components: • 2.5 kg sealing material (typically, ETFE, PTFE, FEPM and FFKM; seal-on-MEA assumed) • 0.2 kg ionomer carrying sulfonic acid groups (in the ionomer membrane, reinforced with PTFE) • 0.15 kg PTFE in the gas diffusion layer (GDL; protection around the ionomer membrane) The weights presented above per component clearly show that the largest volumes of fluorinated material are in the sealants, whereas the amounts in catalyst-coated membrane (CCM) and GDL are much lower. Switching to a different sealing concept, i.e., using a metal-bead seal with an elastomer layer will reduce the amount of elastomer significantly compared to an injection-moulded volume seal. Using the same data, without consideration for possible ameliorations and assuming the CCM and GDL will still contain fluorinated compounds by then, this distribution would imply a PTFE need of 44.25 tonnes, and an ionomer (e.g., Nafion) need of 3.25 tonnes to reach an indicative 1 GW of fuel cell capacity. Based on a

		prospective demand of 100,000 fuel cell trucks and 1,000,000 fuel cell light vehicles on the roads by 2030, the total of required ionomer would amount to around 500 tonnes. Yet, there is no clear estimate today on the future fuel cell capacity needs for 2030, aggregating the various applications (all transport modes, stationary applications...) (note 24). Besides, it is obviously extremely unlikely for the fuel cell capacity to be reached by one unique technology, in that case, PEM. The estimation therefore represents an upper bound of fluorinated compound need. In May 2022, the European Commission introduced its REPowerEU Plan (Note 25), which revised upwards the hydrogen targets of the 2020 EU Hydrogen Strategy (Note 26). According to the new figures, the EU will need to secure 10 million tonnes of imported renewable hydrogen and would have to ensure the production of another 10 million tonnes of renewable hydrogen by 2030. It is important to note that the calculations made in the Restriction proposal were based on old and outdated targets (i.e. 40 GW electrolyser capacity until 2030, based on the EU's Hydrogen Strategy). If the EU were to reach its new REPowerEU objective for the production of 10 million tonnes of renewable hydrogen (i.e., ca. 140 GW of electrolyser capacity in terms of electricity input) only with PEM technology (which requires the ionomers), we would need a maximum of 1750 tonnes of ionomers , using the following assumptions: Operating voltage of 2 V, current density of 2 A/cm², 50% of membrane is within the active area, 127 µm membrane is used, basis weight is 0.25 kg / m². In the case of Nafion, nearly all material makes it into the end-product (<10% would be lost in manufacturing). The progress made in reducing membrane thickness, highlighted above, clearly shows potential to reduce this estimated tonnage. Just like for fuel cells, it is extremely unlikely for the electrolysis capacity to be reached by one unique technology, in that case, PEM. The estimation therefore represents an upper bound for the accumulative fluoropolymer use in water electrolysers through 2030, and the actual use is likely to be much lower, also because of the gradual improvements in the technology. It is very difficult to make predictions past 2030 because cell construction, mode of operation, and market size are either unknown or difficult to predict. Hydrogen Europe collects operational water electrolysis deployments. Based on data as of August 2022, there are 106 water electrolysers that are operational today, for which Hydrogen Europe knows the electrolyser technology. This corresponds to 142.2 MW of capacity. PEM represents 83.5 MW from 55 deployments and ALK represents 57.7 MW from 42 deployments. The remaining difference is filled with operational solid oxide, anion exchange membrane (AEM), or other technologies. In addition to the volumes in electrolyser and fuel cell applications, number of fluoropolymer uses in the hydrogen industry is substantial due to their unique characteristics. As it has been evaluated above, a variety of fluoropolymers are being used as valves, sealing devices and other membranes in all stations in the value chain, from production through infrastructure applications to hydrogen-specific end-uses. To give an idea on the volumes, one Hydrogen Europe Member is processing approximately 20 tons of PTFE-based sealing materials per year into wear parts for reciprocating compressors. The PTFE content is on

		average 70 % which gives a total use of PTFE in the manufacturing of about 14 tons. 30 % are collected in-house as waste from machining (~ 4.2 tons). This material can be recycled as described above. The remaining 9.8 tons are used as sealing elements in reciprocating compressors. Thereby roughly 20 % (~ 2 tons) are wear debris entering the industrial processes. The remaining 8 tons are currently reaching end of life in incineration or landfilling, but they could also be recycled after grade-specific collection and purification, as described in Q4. Thus, the whole process of using 20 tons of sealing materials could be reduced to 2 tons of PFAS ending up as waste in industrial processes. Please note that this is the volume of one company in the sector, the cumulative volume of fluoropolymer in sealing devices is difficult to predict. However, based on the same benchmark of 140 GW electrolysis capacity in terms of electricity input (which would amount to around 100 GW in terms of hydrogen output), we can predict that other fluoropolymer use for the sealing materials (especially PTFE) would roughly amount to 8,750 tonnes at manufacturing, resulting in about 4,375 tonnes in the end-product.
		Answer to specific info request 8: Additional input on alternatives in PEM electrolysers, other electrolysers and PEM and other fuel cells: • Membrane o Fluorine-free ionomers and membrane materials have been around in science for decades. However, during all this time it was not possible to make them meet the requirements for hydrogen applications. Research work has been ongoing for hydrocarbon membrane such as sulphonated polyetheretherketone (PEEK) membrane development, for instance (Note 27). The durability is often poor, as oxidation by oxygen radicals, which are inevitably generated at the cathode electrode, occurs. The non-fluorinated membrane concepts are mainly at laboratory or pilot scale, unproven on industrial scales and are still highly immature, lasting only dozens of hours against lifetime requirements of >25,000 hours for fuel cell applications. In PEM electrolysis, membrane support, aromatic chemistries (e.g. sPEEK) have too low durability. Suitable chemistry would need to be found to accommodate for this major barrier. If, and only if, suitable chemistry (with overall reduction of risk through lifecycle) were to be found one day, deployment cycles are in 10-year timeframes, with a minimum of 5-year demonstration period with reasonable scale, i.e. adding another 15 years on top of the time required to find the substance. Although certain indicators of performance of non-PFSA membranes can be excellent, these non-PFSA membranes (such as hydrocarbon) in electrolyser applications have failed to demonstrate a pathway to commercial lifetimes (>50,000h for electrolyser applications) or at relevant temperature (>79°C). You can see in confidential note 5 an illustration of hydrocarbon membrane breaking after 400 hours in use. In fact, to consider the alternatives to be truly commercially viable regarding PEM electrolysers, durability of well beyond 50,000h should be hit, as you can see a Nafion membrane lasting beyond 100,000 hours (confidential note 6). However, so far very few non-perfluorinated alternatives have come close to even 1000, and none to 10,000 hours. Hydrocarbon

		membranes have an issue with certain chemicals that are formed regular operation, like hydroxy radicals (.OH) and hydroperoxy (.OOH) radicals that are generated by HOOH breaking down, which is itself a by-product of any fuel cell or electrolysis process. This radical can easily break down C-H bonds, as well as aromatic and ether linkages. In the 1990s there was great interest in substituting Nafion and other fluoropolymer-based membranes, since those were more expensive and released HF, which can attack the steel bipolar plates. Still, all of these programmes failed to produce viable alternatives. In the 2010s, there was another surge of hydrocarbon membrane interest, as companies have tried non- and partially fluorinated chemistries. From 2013 onwards $30 million has been spent by the United States' Dept. of Energy on membrane/ionomer R&D, including two thirds on non-PFSA approaches (note 28). None of these led to commercial polymers for fuel cells or electrolysers. o In PEM fuel cell Membrane Electrode Assemblies, there are currently durability challenges with aromatic hydrocarbons. The European Clean Hydrogen Alliance project GAIA (2019-2022) (Note 29) supported by €4.5 million of Horizon2020 funding set out to find hydrocarbon alternatives to PFSA ionomer membranes, however found that similar performance is not possible. IMMORTAL (note 30), another project with €3.8 million Horizon2020 funding and ELECTROHYPEM (note 31), a project with EU funding of €1.3 million concluded that alternative membrane technologies known to date are simply too far behind in terms of durability. There are currently no commercially viable hydrocarbon membranes that simultaneously meet the chemical and mechanical durability requirements necessary (Note 32). In PEM fuel cell applications, as membrane support, PTFE has the necessary mechanical durability, dimensional stability upon water uptake, and chemical inertness under radical attack. There are no alternatives, as PPP (polyphenylene) is thermally and chemically not stable, while being not processable at elevated temperatures (>100 °C). One Member of Hydrogen Europe argues that in-house tests for hydrocarbon materials for ionomers and reinforcement were taken for 15 years, concluding that there are significant gaps, e.g. unfit-for-use trade-offs between performance and durability in chemical and mechanical aspects. It would be challenging to identify PFAS alternative porous films as replacement for ePTFE (expanded PTFE) reinforcement for PEM fuel cell applications in short-and medium term. Confidential note 7 illustrates that the hydrocarbon ionomer exhibits poor chemical stability against the PFSA ionomer (1-2 orders of magnitude lower than PFSA) and there are poor trade-offs between performance and chemical stability, especially at hot/dry conditions. Current experience shows that effective additive technologies, including state-of-the-art mobile and immobile additives are not sufficient in enhancing the chemical stability of hydrocarbon membrane ionomers. o In PEM electrolysis membranes, hydrocarbon ionomers are technically not feasible, as they are too stiff, with often no sufficient mechanical durability. Critically relevant characteristics of PFSA polymers, such as proton conductivity, oxidation stability under high anode potentials during regular PEM electrolyser operation, and processability (lower glass transition temperature compared to hydrocarbon ionomers) are not hit by hydrocarbon alternatives. One Member

		of Hydrogen Europe did tests with hydrocarbon membranes in their PEM electrolysers. Confidential note 8 shows the results that the hydrogen level in the oxygen rapidly rose around the 10-hour mark of the hydrocarbon membrane test, representing cell failure of the membrane. This is a typical issue with hydrocarbon membrane technology. o Also in PEM fuel cell applications, hydrocarbon alternatives are poor in situational performance, particularly under reduced RH (relative humidity) of <50% and thus operationally relevant conditions: (Note 33) we experience a strong dependence of electrochemical performance on material hydration, and greater material swelling and dimensional instability. In the catalyst layer, PFSA ionomers are used as they have the unique characteristic of being able to provide both ion conductivity and hydrophobic properties to the electrode catalyst layer. The hydrophobicity is a function of the fluorinated PFSA backbone and is therefore very difficult to replace, as hydrocarbon polymers are inherently not as hydrophobic as fluorocarbons. There are additional issues with implementation in a manufacturing setting, as the new materials' mechanical properties in a membrane electrode assembly cause poor adhesion between the catalyst layer and membrane. Solutions to this problem are unclear and unproven. The timescale to resolve these performance and manufacturing issues would go far beyond the time provided by any of the time-limited derogations. Research activities to replace the conventional perfluorinated ionomers by fluorine-free materials have been ongoing for the last 25 years but so far, no commercial product has indeed been released due to poor oxidation stability. Fuel cell and electrolyser manufacturers are in close contact with the manufacturers of the components to test the materials at relatively early stage and thus identify and qualify promising materials, promote their industrialisation and replace the current perfluorinated compounds, as early as possible. However, building from past experience, it is impossible to know for sure when a validated alternative material may be available in volume. o As for the reinforcement material, promising approaches are currently made to replace the PTFE by fluorine-free compounds like electrospun PBI-type (polybenzimidazole) materials. These electrospun polybenzimidazole-type materials show promise as a fluorine free mechanical support. However, the technology is not validated in PEM fuel cell systems. Considering the time needed to develop an ePTFE- based solution (regarding both performance and manufacturing) that meets present and future requirements, it is estimated that the implementation of this new approach could take min 15-20 years to implement at scale – provided continued success. In addition to electrospun aromatic engineering polymers (PBI, PES), woven monofilament polymers (PEEK, PES, etc) have been experimented with. For example, the European Clean Hydrogen Alliance supported IMMORTAL project focused on fluorine-free polymer nanofiber reinforcements (see note 30), showing promise but necessitating considerable further steps, as these are not drop-in solutions. Electrospun nanofibers, as a class, have poor mechanical strength and today are not able to provide the support needed for PEM electrolysers operated under differential pressure. Woven monofilament supports are limited to thicknesses of approximately 60 microns or more and may not be suitable for

		thinner membranes required to meet performance targets. Regarding the performance of hydrocarbon alternatives to PTFE reinforcements, a chemically stable and mechanically strong porous film is critical as a reinforcement in PEM to achieve the required durability. Confidential Note 9 shows the efficacy of the reinforcement as a trade-off point vis-à-vis current density. It is visible that using state-of-the-art hydrocarbon instead of ePTFE as reinforcement, the composite PEM exhibited poor mechanical stability as well as poor power output. The hydrocarbon reinforcement is significantly worse than 2nd generation ePTFE. In addition, as can be seen on confidential note 10, severe mechanical strength decay was observed for PEM using hydrocarbon reinforcement after exposing the PEM to chemical degradation tests. o It is necessary to mention that beyond PEM electrolysis technologies, the existence of alkaline electrolysis (ALK) technologies would also be jeopardised by the universal PFAS restriction. This is because as a best available technique, the electrolyte necessary for the functioning of the ALK electrolysis – Potassium Hydroxide (KOH) – is manufactured using electrolysis utilising fluoropolymer-based membrane cell technology (eg AGC's Flemion or equivalents). Potassium salt in the form of brine is electrolysed to produce KOH, Chlorine and Hydrogen. An alternative to this manufacturing process is the method used before, whereby mercury cells are used or asbestos. However, returning to this – on top of being illegal – would be ill advised both for performance and for environmental reasons. No other alternative is known today. o Beyond PEM and ALK technologies, Solid Oxide Electrolyte Cell (SOEC) and Anion Exchange Membrane (AEM) electrolysis technologies are necessary to be mentioned. Although SOEC applications do not include fluoropolymers in electrolyser stacks, nevertheless on the module and system level they rely on components with fluoropolymer valves and sealing devices, similarly to other types (like PEM e.g.)The AEM technology's market is nascent; therefore, many different membrane structures are present, some of which include fluorinated components. Please find more information on the different hydrogen technologies under Note 34. • Electrodes o Electrodes or catalyst layers using non-fluorinated, hydrocarbon-based ionomers as binder polymer pose another challenge in research and development due to requirements of high gas permeability in the electrode, as mentioned earlier. These drawbacks are also confirmed by recent academic efforts on fluorine-free Membrane Electrode Assemblies (MEAs) (Note 35). Therefore, in PEM electrolyser applications no know alternative exist; reports on hydrocarbon ionomers as binder in electrolysis electrodes are scarcer than in PEM fuel cell applications, and research on the effects of hydrocarbon ionomers on the electrochemically active surface area (ECSA) and catalytic activity is still missing compared with PFSAs. System design changes will be required, and these specifications are not clear currently. Additionally, there are no protocols for accelerated durability testing for PEM electrolyser membrane – both regarding PFSA and hydrocarbon. The timeframe for development of a hydrocarbon-based solution would be well beyond a decade and there is no guarantee that it will ever work. o Regarding PEM fuel cell applications, there is no sufficient performance in at dry operation, hydrocarbon membranes meet PFSA benchmarks only at high

		humidity; conductivity values at high humidity (<40% RH) are still far from the target for proton conductivity for automotive application (0.1 S cm-1). In the PEM fuel cell catalyst layer, PFSA polymers have no known alternatives, hydrocarbon-based ionomers have an issue with gas permeability, which gets even more critical at lower humidity. At dry conditions (<30% RH) the main issue is the absence of water, which leads to low proton conductivity of not only the membrane but also of the electrode that results in a lower catalyst utilisation. Although the development of highly oxygen permeable hydrocarbon ionomers for the catalyst layers could in theory enable improvement of the performance of fully hydrocarbon MEAs, especially for PEM fuel cell, the development of tailored ionomers had not even started as of 2022. As another consideration, in PEM fuel cell membrane electrode assemblies, PEEK materials have been found to have poor chemical durability, leading to early mechanical failure. In general, the presence of a hetero-atom leads to such issues. (note 35) • Gas Diffusion Layer (GDL) o Hydrophobisation of the GDL is today always achieved using PTFE. Currently, the PTFE impregnation of the GDL cannot easily be replaced and some effort will have to be made to find alternative hydrophobising agents that are as durable as PTFE. It would surely be desirable to set up funding for projects with the aim to find replacement for the PTFE in the GDL, a topic that has been addressed only sporadically in the past, with no success. The European Clean Hydrogen Alliance projects GAIA (2019-2022) and DOLPHIN (Note 36) both set out to identify alternatives to fluoropolymer components, including in the GDL, however they found no alternatives. • Sealing devices o Some provided input was considered under 'gaskets and seals' potential replacement under Table E.134 (Annex E), line on 'PEM fuel cells'. However, data on gaskets and seals a few lines below for 'PEM electrolysers / fuel cells' related again to gaskets and sealings should be merged with the above, as the issue is the same for PEM electrolysers and fuel cells and should be treated as a whole (and not systematically exclude electrolyser). On top of already provided input, Hydrogen Europe would like to remind the following: in Alkaline, in SOEC and in PEM electrolysis technologies, PVDF, PFA, FKM, PTFE are used as sealings, inliners, diaphragms, in ball-diaphragms, seat and butterfly valves for their durability and consistent performance in extreme circumstances. Given the presence of liquids and chemicals, it is imperative that proper sealing exists between the stacks of the electrolysers. In this regard ePTFE tapes are used between the stacks to provide superior sealing. Expanded PTFE not only has a compressibility of up to 60% - allowing it to make a very robust seal even at low torques – but is also weatherable, resistant to chemicals, and highly effective even in extreme pressures. The exact dimensions of the ePTFE tape can vary from project to project, depending on the construction of the electrolyser. However, a thickness of 1.5-2.5mm is typically used with a width of 25-50mm. The tape is easily applied and can even be layered on to itself, eliminating the use of a standard cut gasket. This is relevant because the diameters of the electrolysers can be as high as 2 meters, meaning that a standard cut gasket would be very wasteful. Considering that a 5 MW alkaline electrolyser requires around 500 seals, this saving is

		particularly vital. o In addition, in solid storage technologies, alternatives for fluoropolymer-based valves are required to have low friction, large temperature range, and hydrogen material compatibility. In gas grids, liquid H2 storage or H2 shipping uses, fluoropolymer valves are used for their cryogenic capability, therefore alternatives without fluoropolymers must have hydrogen compatibility and low load sealing (<2N/mm in circumference) with the ability to sustain up to 1 000 bars. Today, there are no alternatives to provide sufficient durability, chemical resistance and the necessary flexibility as fluoropolymer sealings or diaphragms. Based on failed past efforts in research for alternatives, we predict that those will surely be standard for another 10 years at least. Efforts are made to gradually eliminate the fluoropolymers from the sealing materials as soon as possible. Some elastomers without fluorine exist and could potentially be used in the future for this function. As for gas-permeability and cost, these fluorine-free materials are superior to fluorinated elastomers thus also from technical and economical point of view, replacement of these materials is desirable when possible. However, those are not stable in pressurised deionised water, leading to contamination of the MEA, which would lead to irreversible loss of performance. Moreover, those are not as chemically stable, and therefore not sufficiently durable. o Regarding sealing devices for reciprocating hydrogen compressors, there are no available alternatives, proven by available literature and R&D testing. Concisely, the material properties of perfluorinated polymers are unique and impossible to replace in the near future. Restrictions on fluoropolymers, including PTFE and ionomers with bound PFSA, would make several critical applications from water electrolysis, fuel cells, to hydrogen transport technologies unfeasible or would dramatically reduce their service life, efficiency and increase the probability of malfunction (this goes thus far beyond PEM fuel cell only). Such lowering of the performance of essential applications in the hydrogen industry would drastically slow down the ramp up of this nascent industry, potentially killing such a crucial industry for decarbonisation and jeopardising both our climate objectives and industrial competitiveness. All polymeric alternatives' performance, such as that of hydrocarbon membranes, is still very low because they suffer from reduced thermal and chemical stability, reduced efficiency (e.g., higher ionic resistance) and/or inapplicable mechanical properties and have high deterioration rates and short life expectancies. Earlier R&D, as described above has shown that there is no business case for building electrolysers based on hydrocarbon membranes.
		Answer to specific info request 10: As mentioned in our response to question 2(b), there is currently no legislation and harmonised monitoring system for PFAS lifecycle emissions. It is essential to develop a mutual standard or benchmarking system that industrial actors can use, and which can be the basis for targeted legislation on emissions. A binding monitoring, reporting and verification (MRV) system, ideally harmonised across industry and Member States, should be established and implemented across all life stages of fluorinated

		materials of our sectors. Where detected, PFAS emissions should be abated. For end of life, this includes the implementation of binding take-back systems regarding fluoropolymer-containing components and products of our sectors, where the circularity potential offers great opportunities. Industrial actors already initiated work on a proposal on this topic. In a nutshell, addressing emissions (monitoring and abating) on the basis of common standards should be a regulatory priority, as opposed to a complete ban on the materials. Industry-wide emission monitoring and calculation methodologies can be a far more effective tool in dealing with such substances than a blanket restriction, while not impairing the development of entire industries that are fundamental to the economy's decarbonisation. With the proper legislative framework in place to address fluoropolymers' lifecycle emissions, the European Chemicals Agency should propose an exemption for fluoropolymer production and use under the PFAS restriction.

4145	**Date:** 2023/05/18 02:46 **Content:** Scope or restriction option analysis Information on benefits Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** EVA Therapeutics, Inc. **Org. country:** Japan **Attachment:** ref_4145_public.zip	**General Comments:** We would like to appeal for the use of perfluorodecalin (PFD), a fluorocarbon compound with the chemical formula C10F18 (CAS Number; 306-94-5, EC Name Perflunafene), in a recently developed Enteral VentilAtion (EVA) program should be exempted from PFAS restrictions as it is defined as a critical medical treatment designed to save respiratory failure patients. We believe it is essential to emphasize the critical role of PFD in this groundbreaking medical application, which has the potential to save countless lives. The EVA program leverages the unique properties of PFD, including high oxygen solubility and low surface tension, to facilitate gas exchange in the gastrointestinal tract. By doing so, the program offers a promising alternative for patients suffering from respiratory failure, particularly those who may not tolerate traditional mechanical ventilation methods. In light of the significant medical benefits this program provides, we urge you to consider granting an exemption or special permission for the use of PFD in this context. While we understand and respect the intentions behind the PFAS regulations, we believe that the medical device application of PFD in the EVA program should be evaluated on a case-by-case basis, taking into account the following points: 1. Necessity: The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure, with no current viable alternatives. Particularly, as in the rural and remote situations such as natural disaster areas and battle fields where the highly sophisticated equipment like ventilator or ECMO is not available, the EVA could be a viable alternative to enable breathing of respiratory failure patients. 2. Limited environmental impact: The amount of PFD used in the EVA program is minimal compared to their industrial applications. Strict guidelines and protocols can be established to ensure proper disposal

		and containment, minimizing environmental impact. 3. Patient safety: The EVA program will undergo rigorous testing and clinical trials, demonstrating its safety and efficacy for patients prior to its commercial use. Furthermore, PFD used in this medical application do not pose the same health risks associated with PFAS exposure from other sources, since the safety of PFD has been evaluated as an active pharmaceutical ingredient of Fluosol-DA, the FDA approved medicinal product, as well as the medical devices such as Liquivent-D, DESCRIBE PFD Patch, and ALCHIMIA HPF10. In conclusion, the EVA program represents a significant breakthrough in the treatment of respiratory failure patients, and the benefits of using PFD in this medical application far outweigh the potential risks associated with PFAS. We kindly request that you reevaluate the regulatory restrictions on PFD in this context and consider granting an exemption or special permission for their use in the EVA program. EVA Therapeutics, Inc. also supports the statement made by Conference of Fluoro-Chemical Product Japan on the issues of proposed restriction, as per attached in Section IV.
		Answer to specific info request 1: Although the purpose of "EVA" is not currently mentioned in the existing sectors or (sub-)uses, we believe it should be categorized under the sector of "Medical devices" by either adding a new (sub-)use related to patient treatment or the specific use for the purpose of EVA.
		Answer to specific info request 2: In the EVA program, PFD is used as an oxygen carrier, given its inert and biologically compatible characteristics. Although, PFD is used in other purposes, we are focusing on the usage for the EVA in this proposal. In the manufacture phase of PFD, such as distillation, purification, and packaging, all materials used in the production will be collected and recycled. No emissions of PFD is expected at the manufacturing phase due to the tight control of our contract manufacturer. During the use phase, Oxygenated PFD will be injected into the human body through the rectum. The amount of PFD expelled from the body will be determined once we finalize our device design. If PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site.
		Answer to specific info request 3: As mentioned in the previous section, if PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no

		PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site.
		Answer to specific info request 4: As mentioned in the previous section, if PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site.
		Answer to specific info request 6: a. With the EVA program, we utilize PFD, a fluorocarbon compound with the chemical formula C10F18 (CAS Number: 306-94-5, EC Name: Perflunafene). We estimate that this treatment can potentially save approximately 100,000 patients per annum globally. While it is still in the early phase of clinical study, we assume that approximately 0.5 to 1 liter of PFD will be used for each treatment, resulting in an estimated range of 98 to 196 tons per annum when considering its weight density of 1.96 g/mL. If PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site. b. The use of PFD in a recently developed EVA program is defined as a critical medical treatment designed to save respiratory failure patients. The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure, with no current viable alternatives. Particularly, in the rural and remote situations such as natural disaster areas and battle fields where the highly sophisticated equipment like Artificial Respirator or ECMO is not available, the EVA could be a viable alternative to enable breathing of respiratory failure patients. The EVA program represents a significant breakthrough in the treatment of respiratory failure patients and provides numerous benefits in this medical application. c. We currently don’t have enough datapoints to mention the number of companies estimated to be affected for the purpose of the EVA treatment although there are several companies which are providing PFD for medical purpose. d. The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure. The EVA program leverages the unique properties of PFD, such as its high oxygen solubility and low surface tension, to facilitate gas exchange in the gastrointestinal tract. Its effectiveness has been demonstrated through several animal studies, and we have not identified any viable alternatives. The EVA program will undergo rigorous testing and clinical trials, demonstrating its safety and efficacy for patients prior to its commercial use. Furthermore, PFD used in this medical application does not pose the same health risks associated with PFAS exposure from other sources, as the safety of PFD has been evaluated as an active pharmaceutical ingredient in Fluosol-DA, an FDA-

		approved medicinal product, as well as the medical devices such as Liquivent-D, DESCRIBE PFD Patch, and ALCHIMIA HPF10. e. The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure, with no current viable alternatives. g. The EVA program leverages the unique properties of PFD, including high oxygen solubility and low surface tension, to facilitate gas exchange in the gastrointestinal tract. By doing so, the program offers a promising alternative for patients suffering from respiratory failure, particularly those who may not tolerate traditional mechanical ventilation methods. And more, especially, in the rural and remote situations such as natural disaster areas and battle fields where the highly sophisticated equipment like Artificial Respirator or ECMO is not available, the EVA could be a viable alternative to enable breathing of respiratory failure patients. Although it is not possible to estimate the sales and employment impact specifically at this stage, we assume that about 100,000 patients per annum globally can benefit from this treatment through this invention.

4146	**Date:** 2023/05/18 05:01 **Content:** Scope or restriction option analysis Other socio economic analysis (SEA) issues **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes **Attachment:**	**General Comments:** ThreeBond Co., Ltd. supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV. **Answer to specific info request 1:** PTFE thread sealing tape(Proposal for a Restriction, Table 9, P136) The following are uses not listed in the proposed restrictions. 1. Other sealants and adhesives 2. Lubricants 3. Water repellents 4. Refrigerants 5. Cleaning agents 6. Impregnating agents **Answer to specific info request 2:** a 354257kg b Approximate percentages are as follows. 50% incinerated, 50% landfilled, 0% recycled. **Answer to specific info request 5:** The annual emissions of PFAS components contained in the application concerned are approximately 354257kg. **Answer to specific info request 6:** a 1. Use : PTFE sealing tape for screws and bolts threads, other sealants and adhesives Annual emissions: 63877kg 2. Use: Lubricants Annual emissions: 199kg 3. Use: Water repellents Annual emissions: 544kg 4. Use: Refrigerants Annual emissions: 1263kg 5. Use: Cleaning agents Annual emissions : 288350kg 6. Use: Impregnating agents Annual emissions : 24kg b It exhibits high heat resistance, high chemical resistance, high lubricity, water repellency, flame resistance and cooling functions. c It is estimated that 5995 companies in the automotive, electrical and construction sectors will be affected by the unavailability of our products. d There are no heat- or chemical-resistant

	ref_4146_public.pdf [redacted] **Privacy statement:** As it contains our sales information, if the information is leaked, the sales aspect may be affected.	components that can replace PFAS, so it is not possible to develop alternatives. e There is no technical solution. f At present, there is no prospect of a technically or economically viable alternative. g It is clear that the economic losses and number of jobs caused by the restricted use of PFAS are enormous throughout the industry. We use products containing PFAS components in 5995 of our customers. We alone estimate that losses of maximum EUR 25938208 and approximately 1500 jobs will be affected. In view of the above, we consider that PFAS substitutes should be exempted from the proposed restriction, rather than a 12-year grace period, as they are very likely not to be a complete replacement and are for all practical purposes.

4147	**Date:** 2023/05/18 05:45 **Content:** Scope or restriction option analysis Information on benefits Other socio economic analysis (SEA) issues Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Academic institution **Org. name:** Tokyo Medical and Dental University, Institute of Research **Org. country:** Japan **Attachment:** ref_4147_public.zip	**General Comments:** We would like to appeal for the use of perfluorodecalin (PFD), a fluorocarbon compound with the chemical formula $C_{10}F_{18}$ (CAS Number; 306-94-5, EC Name Perflunafene), in a recently developed Enteral VentilAtion (EVA) program should be exempted from PFAS restrictions as it is defined as a critical medical treatment designed to save respiratory failure patients. We believe it is essential to emphasize the critical role of PFD in this groundbreaking medical application, which has the potential to save countless lives. The EVA program leverages the unique properties of PFD, including high oxygen solubility and low surface tension, to facilitate gas exchange in the gastrointestinal tract. By doing so, the program offers a promising alternative for patients suffering from respiratory failure, particularly those who may not tolerate traditional mechanical ventilation methods. In light of the significant medical benefits this program provides, we urge you to consider granting an exemption or special permission for the use of PFD in this context. While we understand and respect the intentions behind the PFAS regulations, we believe that the medical device application of PFD in the EVA program should be evaluated on a case-by-case basis, taking into account the following points: 1. Necessity: The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure, with no current viable alternatives. Particularly, as in the rural and remote situations such as natural disaster areas and battle fields where the highly sophisticated equipment like ventilator or ECMO is not available, the EVA could be a viable alternative to enable breathing of respiratory failure patients. 2. Limited environmental impact: The amount of PFD used in the EVA program is minimal compared to their industrial applications. Strict guidelines and protocols can be established to ensure proper disposal and containment, minimizing environmental impact.

		3. Patient safety: The EVA program will undergo rigorous testing and clinical trials, demonstrating its safety and efficacy for patients prior to its commercial use. Furthermore, PFD used in this medical application do not pose the same health risks associated with PFAS exposure from other sources, since the safety of PFD has been evaluated as an active pharmaceutical ingredient of Fluosol-DA, the FDA approved medicinal product, as well as the medical devices such as Liquivent-D, DESCRIBE PFD Patch, and ALCHIMIA HPF10. In conclusion, the EVA program represents a significant breakthrough in the treatment of respiratory failure patients, and the benefits of using PFD in this medical application far outweigh the potential risks associated with PFAS. We kindly request that you reevaluate the regulatory restrictions on PFD in this context and consider granting an exemption or special permission for their use in the EVA program. Takanori Takebe and Yosuke Yoneyama (Institute of Research, Tokyo Medical and Dental University), and Tasuku Fujii (Nagoya University Hospital Anesthesiology) also support the statement made by Conference of Fluoro-Chemical Product Japan on the issues of proposed restriction, as per attached in Section IV.
		Answer to specific info request 1: Although the purpose of "EVA" is not currently mentioned in the existing sectors or (sub-)uses, we believe it should be categorized under the sector of "Medical devices" by either adding a new (sub-)use related to patient treatment or the specific use for the purpose of EVA.
		Answer to specific info request 2: In the EVA program, PFD is used as an oxygen carrier, given its inert and biologically compatible characteristics. Although, PFD is used in other purposes, we are focusing on the usage for the EVA in this proposal. In the manufacture phase of PFD, such as distillation, purification, and packaging, all materials used in the production will be collected and recycled. No emissions of PFD is expected at the manufacturing phase due to the tight control of our contract manufacturer. During the use phase, Oxygenated PFD will be injected into the human body through the rectum. The amount of PFD expelled from the body will be determined once we finalize our device design. If PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site.
		Answer to specific info request 3: As mentioned in the previous section, if PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no

		PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site.
		Answer to specific info request 4: As mentioned in the previous section, if PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site. No PFD will be handled by the typical recycling industry.
		Answer to specific info request 6: a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use. ; With the EVA program, we utilize PFD, a fluorocarbon compound with the chemical formula C10F18 (CAS Number: 306-94-5, EC Name: Perflunafene). We estimate that this treatment can potentially save approximately 100,000 patients per annum globally. While it is still in the early phase of clinical study, we assume that approximately 0.5 to 1 liter of PFD will be used for each treatment, resulting in an estimated range of 98 to 196 tons per annum when considering its weight density of 1.96 g/mL. If PFD can be collected from the body using a containment system, recycling can be considered. Otherwise, PFD expelled from the body will be incinerated and no PFD as material can be released into the environment in the end-of-life phase when it is appropriately incinerated and destroyed at the proper waste disposal site. b. The key functionalities provided by PFAS for the relevant use. The use of PFD in a recently developed EVA program is defined as a critical medical treatment designed to save respiratory failure patients. The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure, with no current viable alternatives. Particularly, in the rural and remote situations such as natural disaster areas and battle fields where the highly sophisticated equipment like Artificial Respirator or ECMO is not available, the EVA could be a viable alternative to enable breathing of respiratory failure patients. The EVA program represents a significant breakthrough in the treatment of respiratory failure patients and provides numerous benefits in this medical application. c. The number of companies in the sector estimated to be affected by the restriction. We currently don’t have enough datapoints to mention the number of companies estimated to be affected for the purpose of the EVA treatment although there are several companies which are providing PFD for medical purpose. d. 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. The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure. The EVA

		program leverages the unique properties of PFD, such as its high oxygen solubility and low surface tension, to facilitate gas exchange in the gastrointestinal tract. Its effectiveness has been demonstrated through several animal studies, and we have not identified any viable alternatives. The EVA program will undergo rigorous testing and clinical trials, demonstrating its safety and efficacy for patients prior to its commercial use. Furthermore, PFD used in this medical application does not pose the same health risks associated with PFAS exposure from other sources, as the safety of PFD has been evaluated as an active pharmaceutical ingredient in Fluosol-DA, an FDA-approved medicinal product, as well as the medical devices such as Liquivent-D, DESCRIBE PFD Patch, and ALCHIMIA HPF10. e. 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. The use of PFD in the EVA program has proven to be a vital and effective treatment for patients suffering from respiratory failure, with no current viable alternatives. f. For cases in which substitution is technically and economically feasible but more time is required to substitute; ,,, N/A g. 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. ; The EVA program leverages the unique properties of PFD, including high oxygen solubility and low surface tension, to facilitate gas exchange in the gastrointestinal tract. By doing so, the program offers a promising alternative for patients suffering from respiratory failure, particularly those who may not tolerate traditional mechanical ventilation methods. And more, especially, in the rural and remote situations such as natural disaster areas and battle fields where the highly sophisticated equipment like Artificial Respirator or ECMO is not available, the EVA could be a viable alternative to enable breathing of respiratory failure patients. Although it is not possible to estimate the sales and employment impact specifically at this stage, we assume that about 100,000 patients per annum globally can benefit from this treatment through this invention.

4148	**Date:** 2023/05/18 06:18 **Content:** Scope or restriction option analysis Request for exemption **Type:**	**General Comments:** Our company operate fluoroelastomer compounding business in Japan. We make about about 130tons of fluoroelastomer compound every year. Fluoroelastomer polymer is main raw materials , We use at least 100tons of fluoroelastomer every year . Most of them comes from European fluoroelastomer manufacturers. Our compounds is used in automotive , chemical , semiconductior industy. We definately need these fluoroelastomer. Car, industrial machine, chemical plant cannot run without the fluoroelastomers . We request full exemption for fluoroelastomers which is now available in the market.

	BehalfOfAnOrganisation **Org. type:** Company **Org. name:** SAIKO RUBBER CO.,LTD. **Org. country:** Japan **Attachment:** ref_4148_public.pdf [redacted] **Privacy statement:** The attached file is actual SAIKO RUBBER's fluoroelastomer compounding manufacturing and shipment volume in every month in last 3 years. We make this fluoroelastomer compounds as this volume every month.	Saiko Rubber Co.,LTd. supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV **Answer to specific info request 1:** Sector as a whole including automotive industry , chemical industry, semiconductor industry , aerospace industry, military industy. **Answer to specific info request 5:** Saiko rubber makes about 130tons of fluoroelastomer every yaer, We use Fluoroelastomer about 100tons per year. **Answer to specific info request 6:** There is no alternative materials than Fluoroelastomer , which is the same property as fluoroelastomer. Without fluoloelastomer , car cannot be made. Semiconductor cannot be made. **Answer to specific info request 8:** Alternative materials , such as chloroprene rubber, acrylic rubber , silicone rubber , hydrogenated NBR , these polymer cannot stand high temperature , oil resistance which fluoroelastomer has .

4149	**Date:** 2023/05/18 06:43 **Content:** Scope or restriction option analysis **Type:** BehalfOfAnOrganisation **Org. type:** Industry or trade association **Org. name:**	**General Comments:** We have comments on the proposed restrictions. Please see the attachment in Section Ⅳ.

	Conference of Fluoro-Chemical Product Japan **Org. country:** Japan **Attachment:** ref_4149_public.pdf	

4150	**Date:** 2023/05/18 06:52 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Nippon Mektron,Ltd. **Org. country:** Japan **Privacy statement:** The reason is that the protection of our commercial interests, including intellectual property, could be compromised.	**General Comments:** Nippon Mektron,Ltd. supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV.
		Answer to specific info request 1: Electronics and semiconductors (Annex E.2.11.) Electronics
		Answer to specific info request 8: a)Fluororubber (FKM), bisphenol AF, PTFE. b)It is used in HDD stoppers and requires low outgas to prevent HDD reading errors. In addition, the carriage may hit the main component when the HDD is in operation, and low resilience is also required. g) In thermosetting rubber material, it fails to meet the outgas standard and results in a reading error. In addition, in thermoplastic elastomer material, it fails to meet the outgas and low repulsion. From the above, PFAS material becomes essential as a material satisfying the function. If this material can not be used, HDD can not be produced and storage of large data such as cloud services is impossible via the network. In the future, it will be difficult to digitize information required by various industries, and companies that operate mainly on the network will have a great impact on economic activities, for example, management itself will be difficult.

4151	**Date:** 2023/05/18 07:18 **Content:** Request for exemption	**General Comments:** Nippon Mektron,Ltd. supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV.
		Answer to specific info request 1:

		Transport (Annex E.2.10.) electronic equipment
	Type: BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Nippon Mektron,Ltd. **Org. country:** Japan **Attachment:** ref_4151_public.pdf [redacted] **Privacy statement:** The reason is that the protection of our commercial interests, including intellectual property, could be compromised.	**Answer to specific info request 8:** a)Fluororubber (FKM) b)For on-board heat-resistant FPCs applied to SiC semiconductor compatible power devices. The FPCs used are required to have SiC-equivalent heat resistance of 200 degrees Celsius. For this reason, by using an adhesive made of fluororubber (FKM), it is possible to obtain FPC adhesives with little loss of adhesiveness due to thermal degradation even at 200 degrees Celsius for 3000 hours, thus maintaining the long-term reliability of automobiles. g)Alternative materials (Acrylic rubber, epoxy resin) have insufficient heat resistance at 200 degrees C. Molecular breakage occurs due to thermal oxidation degradation, resulting in functional deterioration such as decreased insulation performance due to peeling from decreased adhesion. As a result, there are concerns about adverse effects on the environment, such as malfunctioning of the power system in automobiles and leakage of electrolyte due to fire. In the worst case, this could lead to an accident or fire resulting in a loss of life.

4152	**Date:** 2023/05/18 08:54 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company	**General Comments:** We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. Since various cleaning solutions are used in microplate cleaners, it is necessary to use fluorine-based solutions that have a wide range of chemical resistance. **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on microplate cleaning equipment in the medical analysis field. These members are required to have properties such as low degradability, cleanliness, bending resistance, sealability, non-adhesiveness, and low friction.

	Org. name: [redacted] **Org. country:** Japan **Company name confidential:** Yes	

4153	**Date:** 2023/05/18 08:57 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes	**General Comments:** We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. "Faecal occult blood test equipment and immunoluminescence measurement equipment have chemical resistance to the fluid used, and the surface condition must be good in order for the fluid to flow smoothly, so fluororesin is necessary. . It is unknown whether there is a substitute material product, but if there is a substitute material, it will take about a year to evaluate chemical resistance, leakage, flow rate, and usability." **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on immunoluminescence measurement devices and fecal occult blood test devices in the medical analysis field. These members are required to have properties such as low degradability, cleanliness, bending resistance, sealability, non-adhesiveness, and low friction.

4154	**Date:** 2023/05/18 09:01 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption	**General Comments:** We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. "Thirteen kinds of substances such as hydrochloric acid, DMSO, and dichloromethane are used in filtration and washing equipment for the pharmaceutical industry. It is necessary because only PTFE, PFA, FFKM, etc. are resistant to all chemicals. Since PEEK, PP, and PPS are not resistant, no materials that seem to be resistant to all of them have been found. If a candidate material is found, it will be

	Type: BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes	necessary to conduct chemical resistance and durability tests with all chemicals, and we cannot predict how long it will take." **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on filtration and washing equipment in the pharmaceutical industry in the field of medical analysis. These members are required to have properties such as low degradability, cleanliness, bending resistance, sealability, non-adhesiveness, and low friction.

4155	**Date:** 2023/05/18 09:05 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes	**General Comments:** We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. "About the field of environmental analysis The ozone gas concentration measuring device is controlled while measuring the ozone gas concentration in order to output ozone from the ozone gas generator at a constant concentration. Resins and rubbers that can withstand high-concentration ozone gas have not been confirmed to exist other than fluorine-based ones. Therefore, there is no alternative material, and fluororesin and fluororubber are required. " **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on ozone gas concentration measuring instruments in the field of environmental analysis. These members are required to have properties such as low degradability, cleanliness, bending resistance, sealability, non-adhesiveness, and low friction.

4156	**Date:**	**General Comments:**

	2023/05/18 09:07 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes	We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. "Diabetes diagnostic equipment (liquid chromatograph) needs to be resistant to acidity because it is in contact with the liquid for a long time, even though it is weakly acidic. Also, a slightly corrosive aqueous solution is passed through during cleaning. There have been cases where the use of grade fluororubber has caused the rubber to swell and become unusable. At present, alternative materials other than fluororesin or existing grades of fluororubber cannot be determined. Even if a substitute material is decided, it will take more than 5 years because all of the devices used will need to be evaluated on a yearly basis. " **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on diabetes diagnostic equipment (liquid chromatographs) in the medical analysis field. Properties such as non-stickiness and low friction are required.

4157	**Date:** 2023/05/18 09:09 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:**	**General Comments:** We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. "For general-purpose measuring instruments (liquid chromatographs) for environmental analysis, even though the amount of organic solvent is small, it is required to be resistant to organic solvents because it is in contact with the liquid for a long time. In addition, since it is a general-purpose device and the liquid used by the user cannot be specified, a certain level of corrosion resistance is required. " **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on general-purpose measurement equipment in the field of environmental analysis. These members are required to have properties such as low degradability, cleanliness, bending resistance, sealability, non-adhesiveness, and low friction.

	Japan **Company name confidential:** Yes	

4158	**Date:** 2023/05/18 09:11 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes	**General Comments:** We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. A selenium monitor by chemical form, which is a process monitor that automatically measures the selenium concentration in industrial wastewater on-line, requires fluororesin and fluororubber to handle highly corrosive strong acids such as sulfuric acid and hydrochloric acid. **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on general-purpose measurement equipment in the field of environmental analysis. These members are required to have properties such as low degradability, cleanliness, bending resistance, sealability, non-adhesiveness, and low friction.

4159	**Date:** 2023/05/18 09:13 **Content:** Scope or restriction option analysis Information on alternatives Transitional period Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:**	**General Comments:** We develop and produce valves with high corrosion resistance. Our valves are used in various fields such as medical and analytical fields. "Used for decolorization of treatment liquids in wastewater treatment equipment. Fluoropolymers and fluororubbers are required because there is a possibility of contact with strong acid liquids in this process. There are no other materials that can be replaced at this stage. " **Answer to specific info request 1:** Diaphragms, valve seats, bodies, joints, and actuator members are used in valves mounted on wastewater treatment equipment in the field of environmental analysis. These members are required to

	Company **Org. name:** [redacted] **Org. country:** Japan **Company name confidential:** Yes	have properties such as low degradability, cleanliness, bending resistance, sealability, non-adhesiveness, and low friction.

4160	**Date:** 2023/05/18 09:59 **Content:** Request for exemption **Type:** BehalfOfAnOrganisation **Org. type:** Company **Org. name:** Nippon Mektron,Ltd. **Org. country:** Japan **Attachment:** ref_4160_public.pdf [redacted] **Privacy statement:** As a reason, the protection of our commercial interests, including intellectual property, could be compromised.	**General Comments:** Nippon Mektron,Ltd. supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV. **Answer to specific info request 1:** Electronics and semiconductors (Annex E.2.11.) Electronics **Answer to specific info request 8:** a)Fluororubber (FKM), bisphenol AF, PTFE. b)It is used in HDD stoppers and requires low outgas to prevent HDD reading errors. In addition, the carriage may hit the main component when the HDD is in operation, and low resilience is also required. g) In thermosetting rubber material, it fails to meet the outgas standard and results in a reading error. In addition, in thermoplastic elastomer material, it fails to meet the outgas and low repulsion. From the above, PFAS material becomes essential as a material satisfying the function. If this material can not be used, HDD can not be produced and storage of large data such as cloud services is impossible via the network. In the future, it will be difficult to digitize information required by various industries, and companies that operate mainly on the network will have a great impact on economic activities, for example, management itself will be difficult.