

Substance: Per- and polyfluoroalkyl substances (PFAS)

Annex XV report Third Party Consultation

EC number: -

From 22/03/2023 to 25/09/2023

CAS number: -

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.

Ref.	Date/Type/Org.	Comments
3834	Date: 2023/03/22 09:25 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:  ref_3834_public.pdf	Answer to specific info request 1: Technical textiles

3843	Date: 2023/03/22 18:20 Content: Scope or restriction option analysis	General Comments: Scope of restriction: The proposed restriction does not differentiate between fluoropolymers (such as PVDF, ECTFE, FEP, PFA and PTFE as wells as Fluoroelastomers - FPM, FFKM, ...) and other PFAS. Fluoropolymers have unique properties that distinguish them from other PFAS and they do not have the environmental and
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	Information on benefits Other socio economic analysis (SEA) issues Request for exemption Type: Individual Country: Austria	toxicological profiles associated with some PFAS that are of concern. I strongly believe that the restriction proposal should differentiate between the various types of PFAS based of their chemical composition, their toxicological profile and the production method (e.g. the production of fluoropolymers without flourinated production aids). Not all PFAS are the same and there is no scientific basis to regulate them all the same. Benefits to sociaty Fluoropolymers use brings significant benefits along the value chain, making them essential in numerous technologies, industrial processes and everyday products. Their chemical inertness and resistance to harsh conditions, corrosion and extreme temperatures (hot and cold) are unique properties, required in a wide range of applications. Banning Fluoropolymers will make it impossible be successful with key initiatives of the European Union: the green deal, the sustainable development goals, energy transition and the European Chips Act. Request for exemption I request that Fluoropolymers should be exempted from the REACH regulation. Industrial production of Fluoropolymers can and has to be handled safely in industrial facilities under controled conditions. Answer to specific info request 2: Especially when Fluoropolymers are used in industrial applications, they are collected and properly discharged at the end of life (waste incineration above 800 °C ensures that all PFAS are destroyed, discharged in a proper waste disposal site). Answer to specific info request 5: The European Chips Act wants to ensure that Euroe is able to produce computer chips on large enough scale to become independet from Asia. Production of computer chips requires ultra pure water and ultra pure chemicals. There is no way aroung using pipes, fittings, vales and vessels made from PVDF, ECTFE, PFA and PTFE in this industry.
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3849	Date: 2023/03/23 01:45	General Comments: Please refer to the further outline in the attachment under Section IV.
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Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Denmark Company name confidential: Yes Attachment:  ref_3849_public.docx	Answer to specific info request 1: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 2: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 3: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 4: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 5: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 6: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in
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		order to address specific details of the proposal and to emphasize the special interest of our company.
		Answer to specific info request 7: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company.
		Answer to specific info request 8: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company.
		Answer to specific info request 9: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company.
		Answer to specific info request 10: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company.

3850	Date: 2023/03/23 02:10	General Comments: Please refer to the further outline in the attachment under Section IV.
	Content: Scope or restriction option analysis Other socio economic analysis (SEA)	Answer to specific info request 1: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in

issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Hungary Company name confidential: Yes Attachment:  ref_3850_public.docx	order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 2: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 3: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 4: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 5: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 6: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 7: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a
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		more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 8: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 9: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company. Answer to specific info request 10: We understand that an online information session will be organised on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. We will submit a more detailed statement in the follow-up to this event and in consideration of the further indications in order to address specific details of the proposal and to emphasize the special interest of our company.
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3851	Date: 2023/03/23 09:57 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company	General Comments: We are using fluoropolymers for seals
		Answer to specific info request 1: Petroleum and mining: Fluoropolymer applications Food contact materials and packaging (Annex E.2.3.): Industrial food and feed production

	Org. name:  Org. country: Austria Company name confidential: Yes	
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3852	Date: 2023/03/23 10:31 Content: Scope or restriction option analysis Information on alternatives Information on benefits Type: Individual Country: Portugal	General Comments: The proposed ban encompasses an inconceivable number of material applications. In this sense, a ban on the materials could have far-reaching consequences that are not immediately apparent. Although the benefits of eliminating PFAS are obvious, the disadvantages far outweigh the benefits, and we would end up worse off than we are now. Who is to say that, in addition to the disruption caused by the removal of PFAS, its substitutes would not be even worse? Or (at best) the same? It is critical to develop a strategy that will allow the EU to meet its Green Deal obligations while also implementing a balanced regulatory approach to PFAS. To simply prohibit such a broad range of material usage is a disservice to all, and the approach should be abandoned in favor of a more balanced outcome.
		Answer to specific info request 1: Medicinal products and medical devices.

3853	Date: 2023/03/24 10:30 Content: Scope or restriction option analysis	General Comments: Good morning, We are a manufacturer of elastomeric construction bearings for static and dynamic requirements and supply construction companies in prefabricated construction, track construction and building construction.
		We are also a manufacturer of shrink tubes and coating systems made of fluoroplastics for industrial

	Type: BehalfOfAnOrganisation Org. type: Company Org. name: ESZ W. Becker GmbH Org. country: Germany	applications, which are used in every conceivable industry. From the baker or butcher who provides his lighting with splinter protection to protect his products, to the sensor manufacturer who wants to significantly increase the life cycle of his electronic components, to the engineer who wants the ideal material for aerospace projects that can withstand all extreme requirements and at the same time has hardly any weight. Fluoroplastics such as PTFE, FEP, PFA and the 35 other materials in this group are unfortunately indispensable and irreplaceable due to their properties. PTFE in particular has an almost universal resistance to aggressive media and can withstand high mechanical or thermal loads at the same time. It is used to protect heating or cooling systems in electroplating, but also to transport fresh water in our passenger planes. It is used in the electric motors of our electric cars, where many sensors have to be permanently protected from oils or greases, but also in medical technology in endoscopic instruments used for operations. New areas of application are added every day, as fluoroplastics have a significantly longer service life compared to conventional plastics, but at the same time are harmless to the body and the environment. In our division for elastomeric construction bearings, we use PTFE in our plain bearings, as they are used in bridge construction, building construction and industrial construction. Due to the outstanding sliding properties of the extremely smooth surface, this material helps to ensure the long-term stability of complex structures. We, as a small medium-sized company that processes fluoroplastics, as well as our customers in the construction, industrial, food & pharmaceutical and automotive sectors, will experience significant impairments and will not be able to keep up with competitors from non-EU countries in the long term. Investments in employees and sustainable production facilities will not pay off and our company will suffer entirely due to the resulting losses. There are many plastics that are harmful to our environment and our health. These should also be tested, strictly regulated or even banned. However, fluoroplastics are not part of this and should not be banned just because they are part of the family. The damage to our further development and our economy will be immense. Thank you for your time. Dennis Olschowka Sales Representative of ESZ W. Becker GmbH Answer to specific info request 1: Fluoropolymer applications / Sector as a whole
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3854	Date: 2023/03/24 12:12 Content: Hazard or exposure Environmental emissions Information on alternatives Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Industry or trade association Org. name: I&P Europe - Imaging and Printing Association Org. country: Germany Attachment:  ref_3854_public.pdf	General Comments: Please see attached non-confidential document. Answer to specific info request 1: Our comments apply to use not yet identified in Annex XV restriction report (also see item 6 below) Answer to specific info request 6: See two attached documents (one non-confidential version and one confidential version)
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	Privacy statement: The document includes confidential business information.	
3855	Date: 2023/03/24 14:02 Content: Scope or restriction option analysis Information on alternatives Type: Individual Country: Germany	General Comments: We reject this undifferentiated approach of group regulation and urge the responsible government representatives in the Federal Republic of Germany and the European Union to exempt the fluoropolymers recognised by the OECD*) as safe materials ("PLC" = polymer of low concern) as well as the materials necessary for their production from PFAS regulation or use restrictions. Fluoropolymers should be exempted from all regulatory activities under the REACH restriction. Fluoropolymers can be classified as PFAS based on their molecular structure. However, their toxicological and eco-toxicological profile is essentially different from the majority of PFAS substances. Fluoropolymers that meet the OECD criteria of PLC (= polymer of low concern) are non-toxic, non-bioavailable, non-water soluble and non-mobile molecules and are judged to have no significant impact on the environment and humans. The stability of fluoropolymers can be directly translated into unique and durable performance properties in many applications. For the new megatrends such as green hydrogen, 5G data transmission or e-mobility, fluoropolymers represent the suitable basis on which these innovations become possible in the first place. Answer to specific info request 1: sealing elements made of Fluoropolymers and Fluorelastomers
3856	Date: 2023/03/24 15:42 Type:	General Comments: Dear ladies and gentleman, in our family we need PFAS products. I absolutely don't understand why the EU ignored the information which were given before this consultation. I need various PFAS products in my daily life (e.g. as sealing, lubricant or clothes for my daily travel to the work with the bicycle).

	Individual Country: Germany	Answer to specific info request 1: Medical applications, technical applications, clothes, sealings, lubricants etc.
		Answer to specific info request 2: In the applications which were given above I have no emissions!!!
		Answer to specific info request 3: From my point the current procedures for waste treatment should be fine.
		Answer to specific info request 4: From my point the current procedures for waste treatment should be fine.
		Answer to specific info request 5: I have not sufficient information about the quantites as a total in my private environment.
		Answer to specific info request 6: Please contact separatley in a transparent atmosphere associations such a Diabetes organizations and chemical associations. It is a shame that comments of these organizations are not consoidered enough prior to such consultation.
		Answer to specific info request 7: It can be assumed that a lot of the products cannot be replaced simply. I am wondering how such a prohibition can be published in the current environment. Asian countries and the US have different political and enomical targets. In consequence they will only replace the production if the profit is high enough.
		Answer to specific info request 8: I will gibe an example. Please ask an diabets patient if PFAS for his medical applications can be replaced. Each Patient is an individual. From my longtime experience I assume that a lot of PFAS applications can not be replaced.

3858	Date: 2023/03/27 17:36	General Comments: Dear ladies and gentleman,
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Content: Scope or restriction option analysis Hazard or exposure Environmental emissions Baseline Description of analytical methods Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Germany Company name confidential: Yes	to the current proposal of the PFAS ban we would like to disagree. Today the industry and their employees are highly engaged to participate in and to support the initiatives against the climate change. For the industry and their employees this is also a high risk for themselves. The support of this initiatives requires a stable and a longterm planning of supply chains and production facilities (e.g. over the next 30 - 40 years). This longterm planning is not possible, if certain basics are not given. In our business we must be sure, that the transport chain and plant equipment will be available over decades. Sealings, lubricants and other materials cannot be changed simply by other materials. The longterm planning must be safe for the hydrogen and ammonia initiatives. What will happen if a new sealing will fail in a gas application, and who will take the responsibility? The industry and their employees need a stable legal support. They also need the freedom for creativity. Therefore we kindly ask you to postpone the legislation and to enter with the concerned industry sectors in a closer contact. I kindly over to contact me directly. With best regards Joachim Richter
	Answer to specific info request 1: see above and the offer to contact me
	Answer to specific info request 2: see above and the offer to contact me
	Answer to specific info request 3: see above and the offer to contact me
	Answer to specific info request 4: see above and the offer to contact me
	Answer to specific info request 5: see above and the offer to contact me
	Answer to specific info request 6: see above and the offer to contact me
	Answer to specific info request 7:

		see above and the offer to contact me
		Answer to specific info request 8: see above and the offer to contact me
		Answer to specific info request 9: see above and the offer to contact me
		Answer to specific info request 10: see above and the offer to contact me

3860	Date: 2023/03/28 14:40 Content: Information on benefits Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: United Kingdom	General Comments: Sphere Fluidics is an interested party in the PFAS Chemical Restriction proposal and wishes to submit a use-specific derogation on the grounds cited in the attached letter. The derogation requested is for single cell, spheroid and organoid analysis which advances research and discovery of new medicines in the Life Science community. This submission is on the grounds that there are significant socio-economic benefits to the technology the company supplies, the miniscule quantities of PFAS materials used to generate these effects, the controlled laboratory conditions and disposal routes in place and the fact that there are no immediately available substitute materials. Answer to specific info request 6: Please see our attached letter.
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	Company name confidential: Yes Attachment: ██████████ Privacy statement: Sphere Fluidics does not wish to disclose the number of customers the company has, the volumes of materials used or any of the detail involved in its technology which could be useful to competitors in markets such as China.	
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3861	Date: 2023/03/29 07:30 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Korea, Republic of	General Comments: It is desirable to be recognized as an 'exempt substance' as a substance essential for product manufacturing without substitute substances throughout the industry.
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	Company name confidential: Yes	
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3862	Date: 2023/03/29 08:53 Content: Hazard or exposure Type: Individual Country: France	General Comments: In general, as observed in my home, my family homes, my friends etc., we all have Teflon pans or Teflon kitchen aids that are used since years. Those pans are generally slightly damaged by the regular cleaning process and use. While the providers would argue that when new those pans can be safe (not talking here about the PFAS production or recycling), that when correctly used there is no risk, in reality the consumers are exposed daily due to those « damaged » elements. We should so consider in the PFAS study the reality of usage of the produced goods and not a theoretical use. Thanks for reading me.
		Answer to specific info request 1: Daily use of kitchen aid (pans for instance) containing PFAS do expose the population due to leak of PFAS from the products in the cooked food. A study is needed but it can easily be observed in any European family.

3863	Date: 2023/03/29 10:55 Content: Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company	General Comments: 1

	Org. name:  Org. country: Korea, Republic of Company name confidential: Yes	
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3864	Date: 2023/03/29 16:30 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Leistritz Pumpen GmbH Org. country: Germany	Answer to specific info request 1: PFAS are high technologie polymeres which are irreplaceable in our products, as there are no alternatives for these properties. The mechanical function combined with the chemical functions are unique and a ban would massively limit the application range of our pumps. Necessary pumping tasks in the food, chemical and petrochemical industries could no longer be fulfilled. The PFAS are used in our products only in the inert state.
		Answer to specific info request 6: PFAS a manadtory to fullfill the function of our pumps. PFAS are used as a coating in the pump an the mechanical and chemical fuction cannot be substitute by an other product. Due to the given boundary conditions no other alternative is available.

3865	Date: 2023/03/29 16:34	General Comments: Regulation covers about 10.000 PFAS materials, but only 38 Fluoropolymers. Our objection is to exclude Fluoropolymers completely of this regulation, as they are polymers of low concern according to OECD
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Content: Scope or restriction option analysis Hazard or exposure Environmental emissions Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Lenzing Plastics GmbH & Co KG Org. country: Austria Attachment:  ref_3865_public.zip	scheme. Especially PTFE must be excluded from the ECHA suggestion of regulation.
	Answer to specific info request 1: Medical implants/ devices; Electronics (cables, fuel cell, battery, etc); Sealing; Filtration; Friction Management textiles
	Answer to specific info request 2: 1) Manufacture phase: we convert PTFE polymers in our factory with state of the art technologies under controlled circumstances and continuously measured waste water and air quality with no PFAS emission 2) Use phase: e.g.: Due to the outstanding performance of PTFE in terms of biocompatibility and long term stability with excellent long term data, PTFE is used in class 3 permanent implants (artificial heart valves) without any leachables or emissions in use phase.
	Answer to specific info request 3: Scientific report on waste incineration and thermal recycling: Chemosphere Volume 226, July 2019, Pages 898-906: Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Krasimir Aleksandrov; Hans-Joachim Gehrman; Manuela Hauser; Hartmut Mätzing; Daniel Pigeon; Dieter Stapf; Manuela Wexler
	Answer to specific info request 4: 1) several case studies already proved recyclability of PTFE. (e.g. Upcycling plant Burghausen) 2) we would like to point out, that overall volume of produced PTFE is very low compared to many other chemical substances and materials. Especially when considering only solid PTFE applications and no coatings or other non-solid products the impact is small in terms of quantity (tonnage). 3) The soluble PFAS can and should be strictly regulated, which will reduce relative volumes even more.
	Answer to specific info request 5: All fluoropolymers for essential uses should get permanent derogation, especially following applications: - PTFE components for permanent implant and medical devices - PTFE components for wound management - PTFE components for electronics (cable tape, fuel cell membrane and Ionomers, battery separator, etc) - PTFE components for efficient sealing devices - PTFE components for filter media - PTFE components for friction management - all other sustainable (emission reducing, energy consumption reducing, lifetime increasing) applications of PTFE components
	Answer to specific info request 6:

		PTFE and Fluoropolymers are very expensive and difficult to work with in converting. Therefore they are only used when no other alternatives are available. - PTFE components for implants: long term stability and excellent biocompatibility combined with flexibility and specific surface properties (low friction) are unique; substitution would lead to worse e.g. artificial heart valves - PTFE components for electronics: EU green deal and digital transformation (5G, etc) will not work without Fluoropolymers. E.g. fuel cell membranes but also cables for high frequency applications (such as sensor cables, Microcoax) - PTFE components for sealing devices: no other material can guarantee long term low emissions (e.g. methane); all alternatives will have shorter lifetime and higher leakage due to lower chemical and thermal resistance. Also friction and therefore power consumption will be higher in all pumps. - PTFE components for filtration: emission will be higher as materials get destroyed much faster (e.g. hot gas filters in waste incineration plant) and g) we have 400 employees and a turnover 2022 of 160 Million Euro, which will be totally affected from such a strict regulation. We do not understand that Fluoropolymers are in the same group as soluble PFAS, although they are completely safe and polymers of low concern according to OECD and others. For further details also see studies of: pro-K Industrieverband Halbzeuge und Konsumprodukte aus Kunststoff e.V. Mainzer Landstraße 55 60329 Frankfurt am Main or The European Chemical Industry Council, AISBL Belliard, 40 - 1040 Brussels - Belgium
		Answer to specific info request 7: According to our OEM clients there are no viable technical alternatives for: PTFE components in Medical implants/ devices PTFE components in Electronics PTFE components in sealing devices PTFE components in filtration devices PTFE components in friction management applications
		Answer to specific info request 8: According to our OEM clients there are no viable technical alternatives for: PTFE components in Medical implant / devices PTFE components in Electronics PTFE components in sealing devices PTFE components in filtration devices PTFE components in friction management applications

3866	Date: 2023/03/29 17:20 Content: Scope or restriction option analysis Environmental emissions	General Comments: Potential impact on fluoropolymer semifinished products and their applications Our company Atolli Oy is providing low carbon foot print (LCA) pipelines, seals, valves, vessels for chemical and process industry. When building these pipelines, we are using semifinished products made out of PVDF, ECTFE, FEP, PFA and PTFE. These products have app. 5-10 times more lifetime and several times lower carbon footprint (LCA), than metal or any other alternative material in use. These pipelines
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Information on alternatives Information on benefits Type: BehalfOfAnOrganisation Org. type: Company Org. name: Atolli OY Org. country: Finland Attachment:  ref_3866_public.pdf	are in use of chemical industry, battery industry, food and drug industry etc. The draft proposal to restrict PFAS defines PFAS as substances containing at least one fully fluorinated methyl (-CF3) or methylene (-CF2-) carbon atom and aims to ban the production, processing, import and use of PFAS across Europe. The discussion was originally triggered by low molecule, water-soluble and volatile substances, but the proposal for the restriction does not distinguish between fluoropolymers (such as PVDF, ECTFE, FEP, PFA and PTFE) and other PFAS. Thus, from the current perspective, all fluoropolymers would be affected by the restrictions. Our target is to exclude fluoropolymers semifinished products from all regulatory activities under the REACH restrictions. Wery happy to give You more deatails and case studies!!!
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3867 Date: 2023/03/30 12:33 Content: Scope or restriction option analysis Information on alternatives Information on benefits Other socio economic analysis (SEA) issues	General Comments: The restriction describes the ban on the manufacture and use of over 10,000 substances, including fluoropolymers such as PTFE. The attempt of singular solution of individual environmental problems (which are important, no doubt) and the disregard /misunderstation of the consequences of these decisions is openly shown with this general prohibition of use. In my view, this general ban does not sufficiently take into account the use of fluoropolymers, within the manufacturing processes of the (chemical) industry. To have highly stable and technically tight compounds is necessary to avoid diffuse emissions (of hazardous substances) to meet current emission restrictions for chemical plants. The fluorinated polymers are urgently needed here precisely because of their material properties (long-term stability, resistance to abrasive media, inert surfaces, ...) to achieve technically tight connections and as inliners for equipment (pipes, containers), a replacement is not available for every type of application.
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	Type: Individual Country: Germany	For example I would like to point pharma industry. This application - especially fluoropolymers - contradicts a pragmatic, risk-based approach and endangers both the prosperity achieved in Germany and (and this is the more important aspect for me) the patient's well-being. As a chronically ill person myself, I am dependent on the regular intake of medication and hereby express my concerns about the relocation of chemical drug production to non-European countries. In particular, the corona pandemic has shown massive delivery difficulties. Last but not least, it still should be a goal to preserve jobs in Europe. The question of how European countries and their population want to live and interact with each other socially and socio-economically today and in the future continues to be ignored with such a ban on use and remains unanswered. Answer to specific info request 1: I am surprised: I would love to refer to Annex XV (Table 9) for the sector: chemical industry, but this is not possible, since in this table many - from my point of view partly unimportant - sectors (e.g. ski wax) are mentioned, but not the chemical industry as a sector. Answer to specific info request 2: up to now emissions in the end-of-life phase (for example) in waste water of chemical plants, didn't have to be measured, this has to take place first, before there is considered a ban of all fluor-polymers like ptfe. Answer to specific info request 3: If we talk about incineration there are specific requirements for emission levels and combustion conditions (temperature, time slots for duration in high temperature areas..) for incineration plants, which meet requirements for safe destroying pfas. Answer to specific info request 6: The question is too simple, I would have loved to answer : I dont have specific and assigned information
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		on this topic. Its easy to imagine that for tight joints no substitution up to now is technically available, because it is precisely the material properties criticized within the ban, that are required in a similar way for the production of seals.
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3868	Date: 2023/03/30 12:43 Content: Information on alternatives Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Aseptconn AG Org. country: Switzerland	General Comments: In the pharma and biopharma industry, PVDF, FEP, PFA and PTFE are the only materials for sealing (in this range of conditions, T°, pH, Pression) and are considered topologically safe. We perform toxicological tests (USP CL VI and USP87) as well as leachability tests. There is no other product on the market that can perform the same functions.
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3869	Date: 2023/04/02 11:42 Content: Hazard or exposure	General Comments: I am against subjecting all PFAS to an undifferentiated restriction. In my company, PTFE and PVDF semi-finished products are machined into individual industrial components. The materials are physiologically harmless and fulfil applications that cannot be fulfilled by any alternative materials in the combination of material requirements in relation to the application. My appeal to the acting bodies is that they take a differentiated view of the situation. An undifferentiated ban will inevitably have negative effects on existential future projects of mankind (energy transition, electrification in the automotive industry,
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	Type: Individual Country: Germany	chemical process industry, etc.). The mere persistence of substances is not an acceptable reason to assume that the substance is harmful or dangerous.
3870	Date: 2023/04/02 22:31 Content: Transitional period Request for exemption Type: Individual Country: France	General Comments: Because this consultation is hard to access by the average European citizens (like me) I am fearful that most of the comments will not come from them but, rather, from industrials that are interested against restricting PFAS and may propose biased analyses. Because of that fear I encourage the evaluation panel(s) to not obey to a 'law of the majority' in the comments received. Similarly, I as an end-user am definitely favoring the shortest possible transition period, and the minimum number of exemptions.
3871	Date: 2023/04/03 05:36 Content: Scope or restriction option analysis Type: BehalfOfAnOrganisation	General Comments: In industrial inkjet printers, PTFE, ECTFE, PFA, ETFE, and FKM are used in wetted parts such as pipes, valves, and ink pumps through which printing ink passes. The reason is their chemical resistance to printing inks. Use of PTFE, ECTFE, PFA, ETFE, and FKM is essential and cannot be substituted. Therefore, please exempt "industrial inkjet printers". Answer to specific info request 1: "5. By way of derogation, paragraphs 1 and 2 shall not apply to:" "x. [industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiF]; y. [industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiF];"

	Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential: Yes Privacy statement: -	
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3872	Date: 2023/04/03 12:09 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country:	General Comments: We would request exemption for seals in highly demanding applications, such as the pharmaceutical and semi-conductor industries.
		Answer to specific info request 6: In the case of pharmaceutical and semi-conductor industries, there is currently no suitable alternative.

	United Kingdom Company name confidential: Yes	
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3873	Date: 2023/04/05 11:56 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: CAAST S.p.A. Org. country: Italy	General Comments: In light of the fact that 90% of the materials we use are fluoropolymers or fluoroelastomers, many of which are qualified as compatible for food, pharmaceutical, and medical use, and there are currently no equally valid alternatives, we would like to understand if there is a possibility of excluding these substances (PTFE, FKM, FFKM, FEP) from the list of PFAS substances. Alternatively, we would like to understand if there is a possibility of being exempted from such restriction. Such restriction could lead to a total shutdown of our company.
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3875	Date: 2023/04/06 15:07 Content: Request for exemption	General Comments: we expect that the PFAS regulation shouldnt be affected to the lundustrial Bakeware market because we haven't got an alternative product to replace our Fluoropolymer coatings in terms of release performance cycles yet. If it is must be bunned by ECHA or Reach it shouldnt be before 2030. we are waiting for your approval.
		Answer to specific info request 1:

	Type: BehalfOfAnOrganisation	We are a job coater company for Industrial Bakeware market trays' and moulds etc.
	Org. type: Company	Answer to specific info request 4: Our Fluoropolymer cotaings sytems'release cycles min 3 times better than closest alternative coating system.
	Org. name: PPG	Answer to specific info request 5: we need derogations for In
	Org. country: Turkey	Answer to specific info request 7: we need an derogation for Industrial bakeware.
		Answer to specific info request 9: industrial bakeware market, food industry.

3876	Date: 2023/04/07 11:52	General Comments: THE INCLUSION OF POLYMERS PTFE,FEP,FFKM,FKM,FEPM IN THE ABOVE MENTIONED LEGISLATION IS UNECESSARY. THESE MATERIALS ARE USED IN SEALING PRODUCTS IN INDUSTRY WORLDWIDE WITH NO ALTERNATIVES. MANY CARRY APPROVALS FOR USE IN FOOD AND PHARMACEUTICAL APPLICATIONS WHICH ARE CLASSED AND APPROVED SAFE. AGRICULTURE,AEROSPACE,AUTOMOTIVE,FOOD, PHARMACEUTICAL,SEMI-CONDUCTOR,OIL FIELD AND MANY MORE, USE THESE MATERIALS. TO RESTRICT THEM WOULD HAVE A HUGE NEGATIVE IMPACT WORLDWIDE, FROM PRODUCER TO CONSUMER.
	Content: Request for exemption	
	Type: BehalfOfAnOrganisation	Answer to specific info request 1: AGRICULTURE,AEROSPACE,AUTOMOTIVE,FOOD, PHARMACEUTICAL,SEMI-CONDUCTOR,OIL FIELD - ALL INDUSTRY!
	Org. type: Company	Answer to specific info request 6: BILLIONS IN WORLDWIDE TURNOVER,MILLIONS OF JOB LOSSES, UNIMAGINABLE CONSUMER IMPACT. SPECIFIC FIGURES TO OUR COMPANY ARE ATTACHED CONFIDENTIALLY .
	Org. name: [REDACTED]	
	Org. country: United Kingdom	

	Company name confidential: Yes Attachment:  Privacy statement: CONFIDENTIAL INFORMATION TO THE ABOVE MENTIONED COMPANY	
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3877	Date: 2023/04/10 08:39 Content: Information on alternatives Type: Individual Country: Japan	Answer to specific info request 6: If the European PFAS restriction on fluorine is proposed and production is discontinued, we will not be able to provide a stable supply to our customers, we would not be able to provide a stable supply to our customers because there is no alternative. We would like to avoid such a situation by all means, so we request that the above-mentioned restrictions be abolished.
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3878	Date: 2023/04/10 12:32 Content: Scope or restriction option analysis Baseline	General Comments: The type of our coatings is Teflon, and the main reason we prefer Teflon application is its long post-coating life. We use Teflon in the production of industrial cakes because the pans are long-lasting and the risk of food contamination is much less than other coatings. In addition, last year, we carried out a project to reduce emission and pollution sources, and with this project, we switched from liquid Teflon to electrostatic powder Teflon. When using silicone or ceramic coatings industrially, the coating life is very short (for us, 1/4 of Teflon is less in some cases), which increases costs and labor. The trials in the coating processes we have done give an answer after 1 year at the earliest. Therefore, a ban that will
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Information on alternatives Information on benefits Transitional period Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Turkey Company name confidential: Yes	take place within 2 years will greatly affect the preparation phase. We are in contact with our suppliers, but we want to make coatings without compromising our current process and quality. That's why our suppliers and we need more time.
	Answer to specific info request 1: Industrial cook bake Industrial pan coating
	Answer to specific info request 2: Our contaminated filter waste is halved.
	Answer to specific info request 6: The cost of teflon is much higher than that of silicon, and raw material and labor losses will increase at the same rate due to both the cost to come from here and the frequency of re-coating pans.

3879	Date: 2023/04/10 19:53 Type: Individual Country: France	General Comments: Please ban these products as quickly as possible and limit their emission into the environment to protect European public health and save future medical costs for member states.
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3880	Date:	General Comments:
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	2023/04/11 08:56 Content: Scope or restriction option analysis Environmental emissions Baseline Information on alternatives Information on benefits Transitional period Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Denmark Company name confidential: Yes	None
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3881	Date: 2023/04/11 12:33 Content: Information on benefits	General Comments: SEMICON APPLICATIONS FLUORTUBING TUBES Fluortubing PTFE Tubings, known for its unique properties of chemical resistance, are widely used for delivering liquids in high-tech applications. These tubing are connected and installed to storage tanks
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	Other socio economic analysis (SEA) issues Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Fluortubing Org. country: Netherlands	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: Particles Metal ions Organic matter Oil Oxide film None of these objects should be eluted or found before etching a microprocessor chip, as the purity of the chemicals and surfaces is crucial to ensure the quality of the final product. Due to its unique characteristics, 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, Fluortubing 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 1: SEMICON Answer to specific info request 3:
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		Fluoropolymer manufacturers are working on an incineration study and will submit information during the course of the public consultation period. Also Fluortubing is working on a recycling project.
		Answer to specific info request 5: 5 tons per year PTFE tubings produced for these semicon applications.
		Answer to specific info request 7: Without fluorotubing PTFE tubes for Semicon many jobs will disappear in h SEMICON industries

3882	Date: 2023/04/11 17:15 Type: BehalfOfAnOrganisation Org. type: Industry or trade association Org. name: ██████████ Org. country: France Company name confidential: Yes	General Comments: we use Per- and polyfluoroalkyl substances (PFAS) F for specific textiles and no solution to replace at the moment
		Answer to specific info request 1: all the product which use Per- and polyfluoroalkyl substances (PFAS) with our textile are for military (Airbus Helicopter TIGER AND NH90) and aeronautic, and some medical end products. there is no possibility to replace because of oil characteristics.
		Answer to specific info request 5: we use about 100 kg per year Per- and polyfluoroalkyl substances (PFAS) ; then we would like have a derogation for our products
		Answer to specific info request 6: we don't found any product today to be able technically substitutioned

3883	Date: 2023/04/11 17:52 Content:	General Comments: to include also the fluoropolymers in the scope does not respect the principle of proportionality and the aim of this PFAS proposal. Further a limitation of fluoropolymers will increase risk and negative impact on the EU society related to
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Scope or restriction option analysis Baseline Information on alternatives Information on benefits Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Norway Company name confidential: Yes	safety for humans and environment (ie not achieving transportation CO2 emission legislations and CO2 targets in case of alternative materials (if possible) and designs over the lifetime of a products / application. Answer to specific info request 1: Transportation: in your annex section A.3.11.1.3 "Combustion engine system" and the table under subsection "coatings and finishes" to the proposal you describe polymeric PFAS examples; you have to Add : coatings for fuel lines as well hydraulic brake hoses. Also in your table 8 of the proposal (section E.2.10) you only mention " seals, O-rings and gaskets), please ADD also " hoses and tubes" (ie like for turbo, fuel , engine coolant , oil coolant, hydraulic brake), volumes for the latter contributes about 2 % - 5 % of the total volume you indicate in table A.10 (tonnage per sector) Answer to specific info request 2: waste 4-6 % during the manufacturing of products (hoses and tubes) made out of fluoropolymers will be incinerate > 850 C (ie fully decomposed) Answer to specific info request 5: under point 6 O " vehicles" : based on our calculation of fluoropolymer content in tubes and hoses per vehicle in the transportation sector (passenger car, truck, bus) we estimate the usage at 300 tons globally per year . Answer to specific info request 7: Under point 6 O of table page 4 starting : design- and material changes in the automotive sector are expensive and difficult due to the extensive validation procedures to guarantee safety and performance of the vehicle; in our case of fluoropolymers hoses and tubes (PTFE, ETFE) validation costs can range from Euro 50.000 to Euro 500.000 per case. As fluoropolymers are very expensive, they are the last solution to use because of their unique combination of properties, so only in cases there are no technical alternatives possibles OEM's designing in fluoropolymer materials, these also enables use of biofuels , downsizing of vehicles + engines and hybrids vehicles (due packaging of dual drivetrain). These are fundaments for the automotive industry to go to 100 % electrification , ie achieve existing and future CO2 emission legislations till 2035. Therefor a 12,5 year derogation is needed as 100 % electrical vehicles don't having combustion engines Under point 5 A of table starting page 4 : nowadays there are NON-fluoronated polymerization aids for PTFE available , therefor exclude form the scope respectively max derogation
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3884	Date: 2023/04/12 09:52 Content: Scope or restriction option analysis Hazard or exposure Environmental emissions Information on benefits Transitional period Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Switzerland Company name confidential: Yes	General Comments: Thank you.
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3885	Date: 2023/04/12 11:03	General Comments: Products under discussion here are considered primary packaging, i.e. packaging of medicinal products with direct contact with the drug, therefore covered by the general exemption:
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Content: Scope or restriction option analysis Information on alternatives Information on benefits Type: BehalfOfAnOrganisation Org. type: Company Org. name: Datwyler Pharma Packaging Belgium NV Org. country: Belgium	"Fluoropolymers used in the pharmaceutical packaging sector are subject to requirements of the EU legislation on regulation of medicinal products for human or veterinary use (i.e., Regulation (EC) 726/2004 (EC, 2004), Directive 2001/83/EC (EC, 2001b), Directive 2001/82/EC (EC, 2001a)." - This is also in line with EMA (European Medicines Agency). Therefore we believe it is incorrectly listed under sub-chapter: A.3.10.1.4 Coatings (page 79 of the Annex XV proposal) But should be listed under the Medicinal Products. ----- Importance of Fluoropolymer in our sector - end use application: The halobutyl substrate is a first prerequisite for medicinal rubber closures as they have the lowest permeability for air and moisture, and can be chemically seen be crosslinked in a clean way. The additional FP coating (via film deep drawing) or (via tumble spray coating) applied on top of the halobutyl functions as a barrier for the remaining chemical substances that can migrate from the rubber stopper (e.g. oligomers, anti-oxidants, plasticizers, cross linking residues,...). And the FP coating is inert on itself, to avoid additional adverse reactions with the drug medicine. The FP coated stoppers have proven their performance throughout the years: where expensive stability studies of new drugs at the big Pharma failed in combination with a standard halobutyl stopper, the FP coated version appeared successful. ----- Till date, there is no alternative solution that fulfils the key attribute of showing 'drug compatibility'. Uncoated halobutyl formulations have improved dramatically over the last decades, but do not reach the level of performance when using the FP coating. Alternative materials like PET film as coating, or replacing the complete halobutyl stopper with TPE have not been successful either. Answer to specific info request 1:
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		Products under discussion here are considered primary packaging, i.e. packaging of medicinal products with direct contact with the drug, therefore covered by the general exemption: "Fluoropolymers used in the pharmaceutical packaging sector are subject to requirements of the EU legislation on regulation of medicinal products for human or veterinary use (i.e., Regulation (EC) 726/2004 (EC, 2004), Directive 2001/83/EC (EC, 2001b), Directive 2001/82/EC) (EC, 2001a)." This is also in line with EMA (European Medicines Agency). Therefore we believe it is incorrectly listed under sub-chapter: A.3.10.1.4 Coatings (page 79 of the proposal) But should be listed in the Medicinal Products. Answer to specific info request 3: All medicinal products have 100% traceable supply chain, strictly controlled, 100% is considered medical waste and at the end of life incinerated under controlled conditions and by dedicated companies. Answer to specific info request 4: Medicinal products (due to health and safety reasons) are not allowed to be recycled, but need to be incinerated, under controlled conditions and by dedicated companies. Answer to specific info request 5: 10-50 tons of fluoropolymer are used per year. Answer to specific info request 6: We supply 500 million pcs (which represents also 500 million drug injections), divided over more than 400 product codes for 186 pharmaceutical customers. Each single product was subject of a multi-year stability study by the pharmaceutical companies, including all different steps of clinical trials, after which filing and approval by the Health Authority was needed per country or in case of the US by FDA. Restarting such exercise is virtually impossible and will induce shortage of medicinal products on the market. The most likely scenario is closing down our European manufacturing site in Belgium, for which this FP coated portfolio is their key manufacturing part and transfer the production to our manufacturing sites in the US and in India. Such transfer also needs a re-qualification by the pharmaceutical manufacturer but is more moderate to execute. FP has a high INERTNESS towards drug medicines and acts as a BARRIER material for the Rubber stopper substrate. Below graph shows the barrier effect of a FP coating on the extractable/migrating chemicals from a rubber. The graph shows 2 spectra in mirror effect: above the 0-line the coated rubber, below the 0-line the same but uncoated rubber. Each peak represents an impurity or raw materials migrating out of the rubber. The height of the peak represents the amount migrating out of the rubber. It is clearly visible that the coating not only reduces the amount coming out of the rubber, but in many cases even completely eliminates the impurities coming out. For
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		many drug formulations, certainly the more recently developed (e.g. mRNA vaccines like COVID, oncology, biological based drugs and cell-and-gene therapies), impurities coming from rubber may jeopardize the stability and effectivity of the drug itself and needs to be studied and controlled in ageing stability studies. In specific cases, the uncoated version fails such stability study and the coated rubber is the only option left. Secondly, each impurity needs to pass a safety and toxicological assessment. So, it is in the highest interest of a pharma company to select a rubber closure with the cleanest extractables profile, i.e. the coated version. Answer to specific info request 8: FP coating on closures, serves as INERT BARRIER coating for Extractables and Leachable from the rubber into the drug medicine. FP has a high INERTNESS towards drug medicines and acts as a BARRIER material for the Rubber stopper substrate. Below graph shows the barrier effect of a FP coating on the extractable/migrating chemicals from a rubber. The graph shows 2 spectra in mirror effect: above the 0-line the coated rubber, below the 0-line the same but uncoated rubber. Each peak represents an impurity or raw materials migrating out of the rubber. The height of the peak represents the amount migrating out of the rubber. It is clearly visible that the coating not only reduces the amount coming out of the rubber, but in many cases even completely eliminates the impurities coming out. Datwyler has invested for +10-years to develop a TPE (ThermoPlastic Elastomer) based stopper without success. Many other players trying to enter the market with TPE as well, yet, whereas TPE might replace some straightforward medicinal products, it will not replace the more sensitive medicinal products that require an FP coating. Datwyler recently finalized the development (~10 years development) of their 'cleanest rubber formulation ever', and albeit it has a very good Extractables and Leachable profile, it will not and cannot replace a FP coated variant.
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3886	Date: 2023/04/12 11:35 Content: Scope or restriction option analysis Type: Individual	General Comments: Fluoropolymers are classified as non-hazardous. There are many technical processes in which these coatings are without alternative. A ban would lead to the outsourcing of production to third countries.
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	Country: Germany	
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3887	Date: 2023/04/12 19:19 Content: Scope or restriction option analysis Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Ireland Company name confidential: Yes	General Comments: General comments: A complete list of uses and the relating functionalities would be too long to list. Fluoropolymers play an important role in virtually all industries. Within the sealing industry alone, the uses would run into hundreds of thousands of applications, each one reliant on the unique combinations of properties found with fluoropolymers (both fluoroelastomers and fluoroplastics such as PTFE): • Chemical resistance • Thermal resistance • Mechanical properties • Low permeability • Low leachable and extractable content • Low surface energy • Low flammability (cannot sustain a flame) • Low friction • High levels of cleanliness (impurities measured in parts-per-trillion in some cases) The strength of the carbon-fluorine bond and the polymeric structures of these polymers is unsurpassed. In the years since their developments in the 1950s, there has been no success in finding alternative materials which can serve to replace or improve on their performance – a period of almost 70 years. There are no technical alternatives available to fluoropolymers in all applications. This is not for the want of trying. It is also not related to cost/benefit drivers. For example, perfluoroelastomers (FFKMs) have a market price more than Eu1000/kg, with some varieties costing three times that. These polymers are used as a last resort where other products and/or designs cannot be used. With 70 years already passed since the commercialization of fluoropolymers, the chances of discovering and commercializing new alternatives within a timespan of proposed derogations (up to 13 years) is extremely unlikely if not impossible. The derogations are contradictory - they immediately ban the monomers but leave derogations for the polymers. So even though fluoropolymers could be used in areas covered by derogations, the
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	Attachment: Privacy statement: Business / commercial information included	restrictions on the monomers prevents the polymers being produced or imported. The list of sectors and sub-sectors considered is incomplete and lacks clear definition. Examples include: • Commodity items: - o There is a large variety of commodity items such as sensors, valves, electrical systems which are used across various sectors. For example: an oxygen sensor may use PTFE as a sealing device (for chemical and thermal resistance, high purity, low outgassing etc) – this could be used for automotive applications, in the energy sector, in a pharmaceutical plant. How would these commodity items be treated? • Petroleum & mining industry - what is the definition of ‘petroleum industry’? Within the definition of ‘Petroleum’ the following is not clear: - o Does this use cover the exploration, drilling, fracking, extraction and treatment (refining, cracking etc.) of oil, gas and related products? - o Does this include Enhanced Oil Recovery using carbon dioxide? • Energy. The following sub-sectors do not appear to have been considered: - o Carbon Capture, Utilization and Storage (CCUS). - o Geothermal Energy - o Hydrogen storage and hydrogen generation Health and Safety Executive (HSE), UK. HSE, the regulator for UK REACH, has worked with the Environment Agency to produce: “Analysis of the most appropriate regulatory management options (RMOA). Substance Name: Poly- and perfluoroalkyl substances (PFAS)”, dated March 2023. Of particular note is the differentiation between polymeric and non-polymeric PFAS, specifically: “In the most comprehensive British analysis of these chemicals ever, the Health and Safety Executive (HSE) has identified the most common and most harmful uses of PFAS and what measures could be put in place to control and manage them. The analysis considers existing laws and also how PFAS substances are being managed around the world, including Europe, Asia and the USA. For the PFAS substances considered in this RMOA, the available data do not indicate a clear association with any adverse health risks. However, the long-term effects of exposure to these persistent chemicals are not well understood, and toxicological data are limited. The underlying chemistry of PFAS (strong C-F bond) contributes to their persistent nature, which in turn leads to greater potential that they could
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		cause serious and/or irreversible damage to the environment. PFAS families may be divided into two primary categories; non-polymeric and polymeric. Polymeric PFAS: Polymers have a somewhat special status in UK and EU REACH in that they are exempt from the registration requirements. Instead of registering polymers, the monomers and other reactants that comprise the polymer are registered in their place. However, polymer substances are not exempted from other parts of REACH. As such polymers – including polymeric PFAS – may be subject to restriction under REACH. The monomers that comprise the polymers may also be covered by the restriction provisions of REACH, if required... It is noted that because monomers used to create polymers are de facto intermediates, these monomers would be exempted from any authorisation provisions of REACH. Information submitted during the GB call for evidence suggests that fluoropolymers and fluoroelastomers are particularly important to the industrial, automotive, aerospace and defence sectors, where uses include membranes, diaphragms, gaskets, seals and pipe linings. The majority of industry responses to the GB call for evidence took the view that whilst alternative substances exist for some uses, the performance would be poorer and might require greater mass of the substitute. For fluoropolymers and fluoroelastomers, the industry view appears to be that for many or most uses there are no alternatives with the requisite performance characteristics. Petroleum and Mining: Tonnage in use Polymers 350-751 t/y; Estimated emissions 0.031 – 0.067 t/y Within this RMOA, risks from polymeric PFAS have been assessed in terms of the groups representing UK REACH registered PFAS monomers and processing aids. Potentially persistent polymer degradation products are considered within the relevant arrowhead groups. However, no attempt has been made to assess the likely levels of emissions of non-polymeric PFAS during service life and disposal of polymers. It is the case (more than likely) that PFAS are present in small quantities in semi-finished or finished imported goods (articles), but there is no requirement to register these imports unless the articles are designed to intentionally release the PFAS during service life and the aggregate import exceeds one tonne per year. Importers/suppliers may in any case be unaware of their presence, due to commercial confidentiality. The Agency concludes that it would be appropriate, considering the Precautionary Principle, to initiate some or all of the following risk management measures with regard to certain uses of PFAS: 2. UK REACH authorisation of PFAS used in processing aids in the manufacture and processing of fluorinated polymers
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	The Agency has concluded that, based on the information gathered in this RMOA, a targeted restriction or a number of targeted restrictions would be a more effective regulatory option than authorisation for minimising releases of PFAS to the environment, including from polymers and imported articles and looking at substances of concern due to wide dispersive use, high emissions or indications from monitoring data. The preparation of any restriction dossiers would require substantial resource, in particular to refine emission estimates to ensure the targeting is appropriate, and data gathering for a socio-economic analysis, taking into account the availability and technical performance of alternative substances.” Answer to specific info request 1: Use and sub-uses: • Fluoropolymers used as packing elements, seals, gaskets, anti-extrusion devices. Sectors and sub-sectors: • Commodity items: o There is a large variety of commodity items such as sensors, valves, electrical systems which are used across various sectors. For example: an oxygen sensor may use PTFE as a sealing device (for chemical and thermal resistance, high purity, low outgassing etc) – this could be used for automotive applications, in the energy sector, in a pharmaceutical plant. How would these commodity items be treated? • Petroleum & mining industry - what is the definition of ‘petroleum industry’? Within the definition of ‘Petroleum’ the following is not clear: o Does this use cover the exploration, drilling, fracking, extraction and treatment (refining, cracking etc.) of oil, gas and related products? o Does this include Enhanced Oil Recovery using carbon dioxide? • Energy. The following sub-sectors do not appear to have been considered: o Carbon Capture, Utilization and Storage (CCUS). □ Uses and sub-uses: Low temperature and exposure to supercritical CO2 requires specialist sealing systems. Seal stacks utilizing PTFE are common due to permeation resistance, low temperature resistance, resistance to ‘dense’ (e.g. supercritical) CO2. o Geothermal Energy □ Uses and sub-uses: Whilst preparing wells for use in geothermal applications there are a variety of applications for both fluoroelastomers and fluoroplastics. The harsh nature of the application (potential for super-heated steam) means that other competing materials (e.g. EPDM) cannot offer comparable performance in a broad variety of sealing systems. o Hydrogen storage and hydrogen generation □ The adoption of hydrogen as an energy source depends on large-scale storage, which can be provided by geological formations (such as caverns, aquifers, and depleted oil and gas reservoirs) to handle demand and supply changes, a typical hysteresis of most renewable energy sources. Hydrogen Europe has published a substantial review of fluoropolymer usage in hydrogen applications in their “Position Paper on PFAS”, summarizing the uses and sub-uses. Health and Safety Executive (HSE), UK.
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	HSE, the regulator for UK REACH, has worked with the Environment Agency to produce: "Analysis of the most appropriate regulatory management options (RMOA). Substance Name: Poly- and perfluoroalkyl substances (PFAS)", dated March 2023. Of particular note is the differentiation between polymeric and non-polymeric PFAS, specifically: "In the most comprehensive British analysis of these chemicals ever, the Health and Safety Executive (HSE) has identified the most common and most harmful uses of PFAS and what measures could be put in place to control and manage them. The analysis considers existing laws and also how PFAS substances are being managed around the world, including Europe, Asia and the USA. Information submitted during the GB call for evidence suggests that fluoropolymers and fluoroelastomers are particularly important to the industrial, automotive, aerospace and defence sectors, where uses include membranes, diaphragms, gaskets, seals and pipe linings. The majority of industry responses to the GB call for evidence took the view that whilst alternative substances exist for some uses, the performance would be poorer and might require greater mass of the substitute. For fluoropolymers and fluoroelastomers, the industry view appears to be that for many or most uses there are no alternatives with the requisite performance characteristics. Petroleum and Mining: Tonnage in use Polymers 350-751 t/y; Estimated emissions 0.031 – 0.067 t/y Within this RMOA, risks from polymeric PFAS have been assessed in terms of the groups representing UK REACH registered PFAS monomers and processing aids. Potentially persistent polymer degradation products are considered within the relevant arrowhead groups. However, no attempt has been made to assess the likely levels of emissions of non-polymeric PFAS during service life and disposal of polymers." Answer to specific info request 6: b) A complete list of uses and the relating functionalities would be too long to list. Fluoropolymers play an important role in virtually all industries. Within the sealing industry alone, the uses would run into hundreds of thousands of applications, each one reliant on the unique combinations of properties found with fluoropolymers (both fluoroelastomers and fluoroplastics such as PTFE): • Chemical resistance • Thermal resistance • Mechanical properties • Low permeability • Low leachable and extractable content • Low surface energy • Low friction • High levels of cleanliness (impurities measured in parts-per-trillion in some cases) c) Petroleum or energy sectors: There are estimates showing that there are over 3000 companies linked to the petroleum (oil and gas) market. This would not include suppliers to this market, for example companies producing seals, gaskets, sensors, valves etc. which could be used across a variety of industries, nor accompanying services such as accountants, marketing, consultants, advertising, legal etc. d) The strength of the carbon-fluorine bond and the polymeric structures of these polymers is unsurpassed. In the years since their developments in the 1950s, there has been no success in finding alternative materials which can serve to replace or improve on their performance – a period of almost 70 years. There are no technical alternatives available to fluoropolymers in all applications. This
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		is not for the want of trying. It is also not related to cost/benefit drivers. For example, perfluoroelastomers (FFKMs) have a market price more than Eu1000/kg, with some varieties costing three times that. These polymers are used as a last resort where other products and/or designs cannot be used. • Hazards and risks: - o Possible differences in functionality include: - o Shorter service life - o Increased risk of failure due to chemical and thermal degradation leading to potential catastrophic events (e.g., large chemical leaks) - o Reduced service intervals and associated costs due to loss of production time - o Increased servicing costs - o Increase waste to landfill or incineration - o Increased fugitive emissions - o Increased risk of contamination of product (leachable and extractable contents of fluoropolymers are lower than competitive products) e) The early developments of PTFE (and similar polymers) can be found from 1938 though the synthesis of elastomeric polymers containing enough fluorine to impart a significant degree of stability was not achieved until the mid-1950's. Examples of technologies introduced since 1955 which have not been able to replace fluoropolymers: • Silicone polymers (VMQ) - o These suffer badly from poor resistance to chemicals, offer poor permeation resistance and suffer from low mechanical properties - o Poor in terms of outgassing • Fluorosilicone polymers (FVMQ) - o Increased chemical resistance over VMQ polymers, but still offers inferior permeation resistance and low mechanical properties - o Poor in terms of outgassing • Nitrile-butadiene rubber (NBR) - o Lacks the high temperature and chemical resistance offered with fluoroelastomers - o Low purity, poor outgassing • Hydrogenated nitrile-butadiene rubber (HNBR) - o Lacks the high temperature and chemical resistance offered with fluoroelastomers - o Low purity, poor outgassing • Polyacrylate rubbers (ACM and AEM) - o Lacks the high temperature and chemical resistance offered with fluoroelastomers - o Low purity, poor outgassing • Polyphosphazene rubbers - o Lacks the high temperature and chemical resistance offered with fluoroelastomers • Polyaryletherketones (PAEKs) - o The PAEK polymers offer advantages over PTFE in how the strength is maintained at elevated temperatures. However, the chemical resistance and friction properties are both inferior. • Polyimide polymers (PI) - o Offer advantages over PTFE in how the strength is maintained at elevated temperatures. However, the chemical resistance and friction properties are both inferior. With 70 years already passed since the commercialization of fluoropolymers, the chances of discovering and commercializing new alternatives within a timespan of proposed derogations (up to 13 years) is extremely unlikely if not impossible. 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). Possible differences in functionality include: • Shorter service life • Increased risk of failure due to chemical and thermal degradation • Reduced service intervals and associated costs due to loss of production time • Increased servicing costs • Increase waste to land-fill or incineration • Increased fugitive emissions • Increased risk of contamination of product (leachable and extractable contents of fluoropolymers are lower than competitive products) g) In terms of socio-economic impacts, there are two main areas for
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	consideration: • Environmental - o The use of fluoroelastomer and poly(tetrafluoroethylene) offer advantages in the combination of thermal and chemical resistance over all other available materials. Their resistance to combinations of chemical and thermal attack reduces the likelihood of chemical leaks to the environment, including fugitive emissions. The social impacts of chemical leaks are obvious and fugitive emissions have been targeted by increasing legislation across a variety of industries. - o Examples of fugitive emissions: □ According to the International Energy Agency, 20% of the world’s annual 570 million metric tons of methane emissions are fugitive. □ Under the United Nations Framework Convention on Climate Change, industrialised countries (“Annex I countries”) regularly report fugitive emissions. These inventories show stable emissions since the mid-2000s after a decline in the early 1990s and a rebound around 2000. In 2016, fugitive emissions reported by industrialised countries were 1.33 billion tonnes CO2 equivalent compared to 1.57 in 1990, about 85% of which were from the hydrocarbons sector, 15% from coal and a fraction from industry (UNFCCC GHG data) • Economic - o Cost of fugitive emissions, example: □ EPA Source: EPA - Inventory of U.S. GHG Inventory of U.S. GHG Emissions and Sinks 1990 Emissions and Sinks 1990 -2004: \$2billion of lost revenue - o Reduced service intervals and associated costs due to loss of production time - o Increased servicing costs Answer to specific info request 7: The derogations are contradictory - they immediately ban the monomers but leave derogations for the polymers. So even though fluoropolymers could be used in areas covered by derogations, the restrictions on the monomers prevents the polymers being produced or imported. The list of sectors and sub-sectors considered is incomplete and lacks clear definition. Examples include: • Commodity items: o There is a large variety of commodity items such as sensors, valves, electrical systems which are used across various sectors. For example: an oxygen sensor may use PTFE as a sealing device (for chemical and thermal resistance, high purity, low outgassing etc) – this could be used for automotive applications, in the energy sector, in a pharmaceutical plant. How would these commodity items be treated? • Petroleum & mining industry - what is the definition of ‘petroleum industry’? Within the definition of ‘Petroleum’ the following is not clear: o Does this use cover the exploration, drilling, fracking, extraction and treatment (refining, cracking etc.) of oil, gas and related products? o Does this include Enhanced Oil Recovery using carbon dioxide? • Energy. The following sub-sectors do not appear to have been considered: o Carbon Capture, Utilization and Storage (CCUS). o Geothermal Energy o Hydrogen storage and hydrogen generation The strength of the carbon-fluorine bond and the polymeric structures of these polymers is unsurpassed. In the years since their developments in the 1950s, there has been no success in finding alternative materials which can serve to replace or improve on their performance – a period of almost 70 years. This is not for the want of trying. Examples of technologies introduced since 1955 which have not been able to compete. With 70 years already passed since the commercialization
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	of fluoropolymers, the chances of discovering and commercializing new alternatives within a timespan of proposed derogations (up to 13 years) is extremely unlikely if not impossible. In terms of socio-economic impacts and risks, there are three main areas for consideration: • Environmental - o The use of fluoroelastomer and poly(tetrafluoroethylene) offer advantages in the combination of thermal and chemical resistance over all other available materials. Their resistance to combinations of chemical and thermal attack reduces the likelihood of chemical leaks to the environment, including fugitive emissions. The social impacts of chemical leaks are obvious and fugitive emissions have been targeted by increasing legislation across a variety of industries. • Economic - o Cost of fugitive emissions - o Reduced service intervals and associated costs due to loss of production time - o Increased servicing costs • Hazards and risks: - o Shorter service life - o Increased risk of failure due to chemical and thermal degradation leading to potential catastrophic events (e.g., large chemical leaks) - o Reduced service intervals and associated costs due to loss of production time - o Increased servicing costs - o Increase waste to landfill or incineration - o Increased fugitive emissions - o Increased risk of contamination of product (leachable and extractable contents of fluoropolymers are lower than competitive products) Answer to specific info request 8: Use and sub-uses: • Fluoropolymers used as packing elements, seals, gaskets, anti-extrusion devices. Sectors and sub-sectors: • Commodity items: o There is a large variety of commodity items such as sensors, valves, electrical systems which are used across various sectors. For example: an oxygen sensor may use PTFE as a sealing device (for chemical and thermal resistance, high purity, low outgassing etc) – this could be used for automotive applications, in the energy sector, in a pharmaceutical plant. How would these commodity items be treated? • Petroleum & mining industry - what is the definition of ‘petroleum industry’? Within the definition of ‘Petroleum’ the following is not clear: o Does this use cover the exploration, drilling, fracking, extraction and treatment (refining, cracking etc.) of oil, gas and related products? o Does this include Enhanced Oil Recovery using carbon dioxide? • Energy. The following sub-sectors do not appear to have been considered: o Carbon Capture, Utilization and Storage (CCUS). o Geothermal Energy o Hydrogen storage and hydrogen generation In terms of socio-economic impacts and risks, there are three main areas for consideration: • Environmental - o The use of fluoroelastomer and poly(tetrafluoroethylene) offer advantages in the combination of thermal and chemical resistance over all other available materials. Their resistance to combinations of chemical and thermal attack reduces the likelihood of chemical leaks to the environment, including fugitive emissions. The social impacts of chemical leaks are obvious and fugitive emissions have been targeted by increasing legislation across a variety of industries. • Economic - o Cost of fugitive emissions - o Reduced service intervals and associated costs due to loss of production time - o Increased servicing costs • Hazards and risks: - o Shorter service life - o Increased risk of failure due
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		to chemical and thermal degradation leading to potential catastrophic events (e.g., large chemical leaks) o Reduced service intervals and associated costs due to loss of production time o Increased servicing costs o Increase waste to landfill or incineration o Increased fugitive emissions o Increased risk of contamination of product (leachable and extractable contents of fluoropolymers are lower than competitive products)
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3888	Date: 2023/04/13 03:31 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: 株式会社 Org. country: Japan	General Comments:
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3889	Date: 2023/04/13 12:49 Content: Request for exemption	General Comments: According to the current text/exceptions, a chemical substance use as API in medicines are exempt of pfas restrictions but not their manufacturing intermediates/process. The current draft text could have several problems in the future if there is not changes in it.
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Type: BehalfOfAnOrganisation Org. type: Industry or trade association Org. name: [REDACTED] Org. country: Spain Company name confidential: Yes	Europe would lose global relevance and competitiveness in the area of manufacturing active ingredients. Jobs could be lost and businesses closed. Some of these active ingredients have no therapeutic alternative (new drugs/apis) A change of manufacturing site has a regulatory impact for the health authorities, both for API manufacturers and for the pharmaceutical industry. This regulatory change takes a long time and may not be approved. The loss of total control over the manufacture of the Active Ingredients on site, may mean a loss of their quality (quality of raw materials, impurity profile, nitrosamines...) There may be a stock-out/shortage of medicines. In for that we would like to claim to include the MANUFACTURING PROCESS OF APIS IN EUROPE as exeption in the pfas restriction Answer to specific info request 6: According to the current text/exceptions, a chemical substance use as API in medicines are exempt of pfas restictions but not their manufacturing intermediates/process. The current draft text could have several problems in the future if there is not changesin it. Europe would lose global relevance and competitiveness in the area of manufacturing active ingredients. Jobs could be lost and businesses closed. Some of these active ingredients have no therapeutic alternative (new drugs/apis) A change of manufacturing site has a regulatory impact for the health authorities, both for API manufacturers and for the pharmaceutical industry. This regulatory change takes a long time and may not be approved. The loss of total control over the manufacture of the Active Ingredients on site, may mean a loss of their quality (quality of raw materials, impurity profile, nitrosamines...) There may be a stock-out/shortage of medicines. In for that we would like to claim to include the MANUFACTURING PROCESS OF APIS IN EUROPE as exeption in the pfas restriction Answer to specific info request 8: According to the current text/exceptions, a chemical substance use as API in medicines are exempt of pfas restictions but not their manufacturing intermediates/process. The current draft text could have several problems in the future if there is not changesin it. Europe would lose global relevance and competitiveness in the area of manufacturing active ingredients. Jobs could be lost and businesses
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		closed. Some of these active ingredients have no therapeutic alternative (new drugs/apis) A change of manufacturing site has a regulatory impact for the health authorities, both for API manufacturers and for the pharmaceutical industry. This regulatory change takes a long time and may not be approved. The loss of total control over the manufacture of the Active Ingredients on site, may mean a loss of their quality (quality of raw materials, impurity profile, nitrosamines...) There may be a stock-out/shortage of medicines. In for that we would like to claim to include the MANUFACTURING PROCESS OF APIS IN EUROPE as exeption in the pfas restriction
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3890	Date: 2023/04/13 13:24	General Comments: Referring to PFA, PTFE ... Polymers, they represent very selective combined Corrosion and temperature resistance and in many chemical production processes and also very environment and alternative energy relevant processes ther is no alternative for Fluor containing polymers!!
	Content: Information on alternatives	Answer to specific info request 1: Production of Sulphuric acid by WSA (wet) process, production of Epichlorhydrin for Epoxid-resins (main material for wind mill rotors), Productions producing and using Hydrochloric acid and other halogenic acids
	Type: Individual	Answer to specific info request 2: Vessels in the chemical industry are dismatled and recycled at the end of life and it is also applied for PFA-Liners in vessels.
	Country: Austria	Answer to specific info request 3: There are no emissions from Fluorinated Plastics because they are very resistant.
		Answer to specific info request 6: in WSA Sulphuric acid process substitution is only possible by lead, but energy effciencie of the process in much lower. For applications with Hydrochloric acid and other acids in chemical processes the use of enemel and graphite is an alternative, but only very small equipment can be produced and therefore the production processes become uneconomical.
		Answer to specific info request 7: Lead is not HSSE kindly , Energy consumption in the production processes for alternatives are causing

		higher CO2 emissions.
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3891	Date: 2023/04/14 10:54 Content: Scope or restriction option analysis Information on alternatives Other socio economic analysis (SEA) issues Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Datwyler Org. country: Switzerland	General Comments: Fluoropolymers are widely used in many different sectors due to the unique properties they give: • Strong resistance - to low (-40°C) and high (+250°C) temperatures; • Aggressive fluids and fuels resistance; • High resistance to permeability; • Increased lifetime and reliability of components (increasing the safety and also sustainability); • Great compression set at low and high temperatures We provide Fluoropolymer based articles (FKM, PVDF, PTFE, PTFE as surface coating) for these sectors: - Construction materials and products - Petroleum (oil & gas) & mining - Electronics and semiconductors - Energy applications, including batteries and hydrogen - Transportation (Automotive) - Aerospace - Industrial applications (chemical industry) - Water and wastewater treatment Currently there are no alternatives to Fluoropolymers. A replacement is only possible with significant compromises in functionality. In multiple cases functionality of the systems will not be given anymore with alternatives. Other materials can offer similar properties (not the same), but only for one of the multiple characteristics of FP (above mentioned).
		Answer to specific info request 1: We produce rubber articles made with Fluoropolymers (FKM, PVDF, PTFE, PTFE as surface coating) for these sectors: - Construction materials and products - Petroleum (oil & gas) & mining - Electronics and semiconductors - Energy applications, including batteries and hydrogen - Transportation (Automotive) - Aerospace - Industrial applications (chemical industry) - Water and wastewater treatment
		Answer to specific info request 3:

	Fluoropolymers should not be treated as monomeric PFAS. There are no emissions of momeric PFAS into the environment at the end of life of items made with fluoropolymers. For the automotive sector there are IMDS and ELV directives. Both regulate the separation of waste and the end-of-life treatment of such products. We don't have more information on the other sectors. Answer to specific info request 5: - Construction materials and products - 14 Million Pcs. / Year - Petroleum (oil & gas) & mining - 2.5 Million Pcs / Year - Electronics and semiconductors - 4.5 Million Pcs. / Year - Energy applications, including batteries and hydrogen - 6 Million Pcs. / Year - Transportation (Automotive) - 35 Million Pcs. / Year - Aerospace - 3.5 Million Pcs. / Year - Industrial applications (chemical industry) - 40 Million Pcs. / Year - Water and wastewater treatment - 120 Million Pcs. / Year Answer to specific info request 6: By providing durable and effective protection against heat, aggressive fluids and fuels, humidity, vibrations and compressions, they prolong the useful life of various components critical for performance, emission control, and safety to the automotive industry. Replacements of FPs is only possible with significant compromises in functionality. In multiple cases functionality of the systems will not be given anymore with alternatives. Other materials can offer similar properties (not the same), but only for one of the multiple characteristics of FP. E.g. HNBR / ACM / AEM rubber can offer resistance to aggressive fluids (not as high as FKM), but at the same time, it doesn't have the same level of Heat Resistance as would have FKM. For these reason each application must be re-evaluated. It will take several years, involving engineering, R&D, production tests, validations. This variety of properties makes FPs unique as they can cover a wide range of applications compared to other materials in the rubber industry. At the moment, a full substitution of FP-based materials is unlikely. If we stop producing articles with FP-based materials, there will be a significant direct loss of the revenue (20%), with consequence of reorganization (lay-off up to 20% of workers). The indirect loss might be higher as the specific industry (e.g. automotive) comes to a standstill. That may result in a complete stop of turnover, also for non-fluoropolymer related components. Answer to specific info request 7: In the Automotive sector, there are currently no valid alternatives to Fluoropolymer-based products. A ban of Fluoropolymers, will result in a no possibility to use transport vehicles with ICE, not only for new ones but also for existing (spare parts no longer available). This involve: Cars, trucks, tractor, motorbikes, ships, planes, and so on... Since FPs are also essential for developments for battery applications, also hybrid cars and EVs are impacted. All industrial applications would be affected with a
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		reduction of availability and/or increase of cost for consumers in EEA. Additionally, their high resistance to permeability makes them excellent for applications in contact with hydrogen. Answer to specific info request 8: Our FP-based articles are in contact with aggressive fluids (e.g. oils, fuels, greases) and they have strong resistance to low (-40°C) and high (+250°C) temperatures. - Construction materials and products - Petroleum (oil & gas) & mining - Electronics and semiconductors - Energy applications, including batteries and hydrogen - Transportation (Automotive) - Aerospace - Industrial applications (chemical industry) - Water and wastewater treatment Fluoropolymers are widely used due to the unique properties: • Strong resistance - to low (-40°C) and high (+250°C) temperatures; • Aggressive fluids and fuels resistance; • High resistance to permeability; • Increased lifetime and reliability of components (increasing the safety and also sustainability); • Great compression set at low and high temperatures Few uses not identified in the proposal: - FKM O-Rings that are used in the transmission of wind turbines. - FKM O-Rings that are used to seal moulds in the production of Health Care Products. - FKM based seals in H2 Electrolysers. - FKM based developments for battery and fuel cell applications. - Sealing applications in valves for contact with gases (methane and 100% hydrogen -- EU 2030 green hydrogen goal). - FKM O-Rings and other FKM seals are generally preferred by our customers due to their increased durability, compared to other materials (increasing sustainability).
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3892 Date: 2023/04/14 10:58 Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: China	Answer to specific info request 5: Fluorochemical is not alternative to many areas, please consider a derogation for fluoropolymers and refrigerant gas.
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	Company name confidential: Yes Attachment:  Privacy statement: If the PFAS Act is passed, the impact to our company is huge, and the influence to the entire fluorine chemical industry, as well as downstream terminal applications, such as wire and cable, semiconductor, aerospace, medical equipment and other industries is also huge. The development of the industry is inseparable from the support of regulations. We sincerely hope that F-GAS team can consider it, to set up a derogation period or even non-time limited policy for fluorochemicals or for most fluorochemicals end use scenarios, such as wire and cable, semiconductor, aerospace, medical equipment ect. Please check enclosed our data in detail.	
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3893	Date: 2023/04/14 13:11 Content: Scope or restriction option analysis	General Comments: The "PCB pattern direct drawing device" uses PFAS as the contact member that attracts and fixes the printed circuit board to be printed. The reason for this is the purpose of stripping from the contact member without destroying the adhesive resist applied to the printed circuit board. The use of PFAS is mandatory and cannot be substituted. Therefore, please exempt from "PCB pattern direct drawing equipment".
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	Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential: Yes	Answer to specific info request 1: "5. By way of derogation, paragraphs 1 and 2 shall not apply to:"
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3894	Date: 2023/04/14 16:08 Content: Scope or restriction option analysis Hazard or exposure Environmental emissions Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption	General Comments: PFPE and PTFE are used in medical device lubrication. These lubricants are not metabolized and show no toxicity according to our tests (see confidential data). The products are extremely expensive (up to several thousand €/kg) and therefore are only used, where necessary in the lowest necessary amount. Therefore the potential emission is also extremely low. So, all in all we have non-toxic products, that do not reach the environment in considerably amounts. A restriction is therefore not justifiable. In our opinion, due to the huge socio-economic impact of a restriction of PFPE and PTFE on the medical care (hospitals and doctors could not work any more, like before; see below), together with the low toxicity risk, an exemption should be considered: - total exemption without any transition period for PTFE and PFPE used in all sectors or - total exemption without any transition period for PTFE and PFPE used in medical sectors Additionally, we plead to derogate the use of the monomers for the above mentioned polymers in the production of PFPE and PTFE. If only the above mentioned polymers are exempted in the EU, the products have to be produced in other countries which leads to a marked disadvantage for the EU. And in other countries the awareness
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	Type: BehalfOfAnOrganisation Org. type: Company Org. name: Boss Lubricants GmbH & Co. KG Org. country: Germany Attachment: [REDACTED] Privacy statement: The information given as confidential information is a market advantage and shall therefore be protected to ensure our commercial interests. Additionally, the information of the composition of the product is our intellectual property and has to be protected.	for the environment might be not that high, as it is in the EU. In the end this could lead to higher pollution of the world as a whole. Answer to specific info request 1: Sectors: Medical devices and Lubricants PFPE and PTFE are important components in lubricants for medical industry. They are not metabolized and have one of the best toxicity-profiles (see confidential data for information on cytotoxicity, hemocompatibility, systemic toxicity, pyrogenity). Answer to specific info request 2: Estimated emission share for manufacturing phase: <0,01% (products are quite expensive and therefore carefully prepared to minimize wasting). In production of 100 kg PFPE/PTFE-grease about 50-100 g stick on the machines (vessels, roll mills etc.). These 100 g are carefully cleaned up and disposed to incineration, so usually there should not be an emission to the environment at all. Estimated emission share for use phase: <0,01% (the PFPE/PTFE-based lubricants in medical devices are made as a lifetime lubricant, so emission is only due to loss on leakages. Leakages are rare, as the medical devices are usually sealed). Estimated emission share for end of life phase: <0,1% PFPE and PTFE based lubricants that are used in medical applications (implants, medical devices) are disposed together with the parent device. As these typically are either potentially infectious (e.g. removed implants) they are incinerated. As the incinerators have HF-filters, total emissions are supposed to be low. Non-infectious devices are usually disposed together with electronic or general hazardous waste. As these are also incinerated or molten, where the PFAS decompose, here also total emissions are supposed to be low. Answer to specific info request 5: Taking into account our market share (in our opinion we are one of the three main producer for special PFPE/PTFE lubricants in medical applications) for PFPE/PTFE lubricants in medical applications, we estimate the amount of these PFAS as a lubricant in medical devices to be 1-10 tons/year. Estimated emission to the environment: <0,1% Answer to specific info request 7: We suppose, that for PFPE/PTFE based lubricants for medical applications the derogation 5s is suitable, as without these lubricants no safe use would be possible. As product development time for medical devices can be quite long, even 13.5 years could be a quite short transition time. Please check for the comments of medical device manufacturers. Answer to specific info request 8:
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		PFPE/PTFE-based lubricants for medical applications might fall in a first instance under "lubricants not used under harsh conditions", as temperature and atmospheric conditions are not harsh. However, the requirements for those lubricants are extremely high: a) long time stable for life-time lubrication (especially in implants) b) non-soluble in water or in body liquids c) not mobile in the body d) non metabolizable in humans and animals e) non-cytotoxic f) hemocompatible g) non-pyrogenic h) not systemic toxic i) do not form decomposition products during application j) do not contain unwanted impurities from raw material production product manufacturing k) can be sterilized for re-use in hospitals and at doctors All these requirements can only be fulfilled with PFPE/PTFE based lubricants. There is no other chemical composition known, that fulfill all the requirements at once. Therefore, without PFPE/PTFE-based lubricants no surgery with the help of electro-mechanical devices (power tools, saws, drills,... surgery robots, ecmo-systems,...) would be possible any more and also mechanically active implants (pumps, screw drives,..) would not be available in the known situation.
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3895	Date:	General Comments:
	2023/04/14 17:26	The contribution is listed in the appropriate section
	Content:	Answer to specific info request 1:
	Scope or restriction option analysis	Any fluoropolymers sectors and sub-uses
	Hazard or exposure	Answer to specific info request 3:
	Environmental emissions	Nearly 100% of the fluoropolymer processed is incinerated at the end of its useful life. Chemical plant operators dispose of chemically contaminated pumps and valves by incineration. The annual fluoropolymer quantities can be found in the Appendix
	Baseline	Answer to specific info request 4:
	Description of analytical methods	Dry and clean mechanical PFA chips (5to p.a.) are processed for cable sheathing (PFA). Wet chips are disposed of via the waste disposal company (1to p.a.)
	Information on alternatives	Answer to specific info request 5:
	Information on benefits	100to p.a. PFA are proceed for pumps and valves. The Fluorpolmere are conform to the latest REACH PFAS restrictions. The PFAS limits are confirmed by the manufacture as well as an external labratory. The PFAS values are smaler in the final product than in the resin after processing.
	Other socio economic analysis (SEA) issues	Answer to specific info request 6:
	Transitional period	
	Request for exemption	

	Type: BehalfOfAnOrganisation Org. type: Company Org. name: Richter Chemie-Technik Org. country: Germany Attachment:  ref_3895_public.xlsx	Detail data are in the Excel Spread Sheet form the downstream User Questionnaire_SEIA data collection_20230210
		Answer to specific info request 7: Detail data are in the Excel Spread Sheet form the downstream User Questionnaire_SEIA data collection_20230210
		Answer to specific info request 8: Detail data are in the Excel Spread Sheet form the downstream User Questionnaire_SEIA data collection_20230210
		Answer to specific info request 10: There is no practical measuring equipment to robustly measure the current REACH restricted PFAS emissions (ppb) in production areas such as ovens and ventilation systems. There are no global standards for measuring REACH-restricted PFAS in primary and finished materials such as PFA granules and PFA liners.

3896	Date: 2023/04/17 10:26 Content: Scope or restriction option analysis Environmental emissions Baseline Information on alternatives Other socio economic analysis (SEA) issues Transitional period	General Comments: Envirotainer General Comment: We suggest a separate 13.5-year derogation for actively refrigerated containers for pharmaceutical air freight (ULDs). This solution, according to an ongoing analysis that we will provide at a later date, is the only way to ensure enough development time. We suggest a derogation for: “Refrigerants in active temperature-controlled containers certified for air freight by European Union Aviation Safety Agency (EASA) until 13.5 years after EIF;” Alternatively, clarifying the definition of "Transport Refrigeration" to include active ULDs would help in securing some time under the transport derogation. However, we believe this would give insufficient time to develop a PFAS-free alternative due to the aviation safety constraints governed by EASA.
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Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Envirotainer AB Org. country: Sweden Attachment:  ref_3896_public.pdf  Privacy statement: Contains business critical information.	Active refrigerated ULDs (Unit Load Devices) are mainly used for medicine transport (vaccines, biopharmaceuticals) in air freight and are an essential aspect that Annex XV has not addressed. These ULDs, with active refrigeration systems, are rigorously regulated by aviation authorities such as EASA/FAA, adhering to stringent safety, weight, and dimension requirements. The significance of active refrigerated ULDs cannot be overstated, particularly for the transportation of sensitive pharmaceuticals. Recognizing the importance of PFAS restrictions for public health, it is still crucial to establish a transitional period to ensure the uninterrupted operation of the active pharmaceutical cold chain. Due to the combination of Annex XV and F-Gas Procedure 2022/0099/COD, the only remaining alternative refrigerants for ULDs are natural refrigerants. Due to stringent safety standards, it will take up to 12 years to develop a safe solution for air freight using flammable options. For non-flammable options there has been a lack of component development to the size, efficiency, and weight constraints of ULDs. Please see the attached main submission letter for details as well as contact information for additional data. Answer to specific info request 1: Envirotainer Comment: Our comment concerns a specific sub-use not explicitly stated in Table 9 of Annex XV. However, we believe that this sub-use has enough commonality between some sub-uses stated in Table 9 to fall under the same definition, if allowed for some amendments. Sectors: Applications of Fluorinated Gases, Transport Relevant sub-uses: Refrigeration, Transport Refrigeration, Mobile Air Conditioning The analysis of Annex XV states that the above sub-uses have no technically or economically feasible alternatives at EIF. These sub-uses receive derogations of between 5 and 12 years. Actively refrigerated Unit Load Devices (ULDs), face higher challenges than the above sub-uses. Due to stringent safety, weight, and dimension regulation from European Union Aviation Safety Agency (EASA) more time is required to develop solutions. There is currently low substitution potential for refrigerants due to: Safety concerns using flammable natural refrigerants require a derogation period to develop safety and redundancy systems in case of damage or leakage on-board a plane. Also, additional time is needed for the extensive validation process from EASA, forwarders, and airlines. Component availability/development is not yet mature for non-flammable refrigerants such as CO2. A derogation period would ensure enough time to develop systems using these safe natural refrigerants. We request the use of active refrigerated ULDs be given a derogation period due to similar reasons to the sub-uses mentioned above. A specific derogation for this field is the best option to ensure and un-interrupted cold
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	chain.
	Answer to specific info request 2: Envirotainer Comment: See attached “Question 2 - Emissions in the end-of-life phase (Confidential)” pdf file.
	Answer to specific info request 6: Envirotainer Comment: See attached “Question 6 - R&D Processes (Confidential)” pdf file.
	Answer to specific info request 8: Envirotainer Comment: The market for temperature-controlled airfreight solutions used for transporting pharmaceuticals consists of passive and active solutions. Active solutions (using a compressor driven temperature control system) constitute a tangible (ca 20%) and growing share (Active growing at +15% CAGR vs. ca +7% CAGR for passive) of the market. During recent years, the pharma industry has transitioned from chemical treatments to biological, so-called large molecule, treatments. The growth of the market is driven by the underlying growth of these biological pharmaceutical treatments, which are used e.g., for oncology, diabetes treatments, vaccines etc.), but also novel modalities, cell & gene, and during the pandemic mRNA treatments. The need for international air transportation of pharmaceuticals is driven by the extreme temperature sensitivity and high value of these shipments, where air transportation is paramount, as the only alternative - sea shipments - is in most cases is not an option due to the time required (months) and the risks of experiencing temperature excursions (making the treatments ineffective or dangerous during such a long shipment. Also, the complexity of demand planning for the supply chain of these treatments results in the need for just in time deliveries from single manufacturing sites to global markets, which again requires air transportation in order for patients to reach their life critical treatments in time. Active solutions in particular are specifically designed for airfreight and in addition to complying with strict pharmaceutical industry regulations, also complying with air safety regulations. Their specific design enables more cost-effective shipments (resulting in lower cost of treatment for the patient), and more sustainable shipments (CO2 emission savings of up to 90% vs. passive solutions). Envirotainer’s market share is ca 10% of the total market. In 2022, Envirotainer supported shipments of ~750 million doses of life critical pharmaceuticals. In addition, Envirotainer played a key role in the global distribution of covid vaccines and treatments, supporting shipments of well over 1 billion doses of covid vaccines. We will strive to input more data and analysis into the consultation in future comments.

3897	Date: 2023/04/17 12:26 Content: Hazard or exposure Information on alternatives Other socio economic analysis (SEA) issues Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Hardick B.V. Org. country: Netherlands Attachment: ref_3897_public.zip	General Comments: We produce PTFE coated high temperture resistant conveyor belts and related products. We have been doing that for over 40 years. We have undertaken many risk assessments in that time, by both internal workers and external parties. No specific risks on our use of PTFE did ever came out, nor did we ever had a stakeholder that lost its health due to our processes or products. Because of the demands of our conveyor belts being high temperature resistance and non stick there is no general, well functioning alternative. Our belts are very expensive, an alternative would hence have a good opportunity in our market but has so far not been found. We supply our belts and products to about 1000 annual customers (from small businesses to multinationals) all over the world. 70% of our sales is exported, more than half of that export goes to other EU companies. If PTFE and PFA remain on the banned PFAS list, we have no alternative than to close our company and letting go over 50 employees. At many of our customers the same will happen as there are not many alternatives for our belts. PTFE (and PFA) as a fluoropolymer has different properties than the general PFAS-substance. PTFE (and PFA) is not hazardous in use or in waste streams. With banning PTFE (and PFA) the EU will give a major advance to the USA, India and China (and basically rest of the world) in production and distribution of necessary tools, products and machines for every day life usage and for innovations. Answer to specific info request 1: We produce PTFE coated conveyor belts, tapes and sheets. Apart from sector Industrial food and feed production this application is not mentioned in Table 9. More information is given in the attachement. Answer to specific info request 6: We are a small company (40 FTE), but relatively large in our market of PTFE conveyor belts, tapes and sheets. a: Our annual usage is about 40 tons of PTFE in our closed PTFE coated materials and about 20 tons of PTFE in our mesh materials. On top of that about 5 tons of PFA in our films. b: PTFE and PFA secure high temperature resistance, non-stick, low friction, stability of the fabrics c: In NL minimum 3 other companies as ours, in Germany 10. Probsbly more than hundred in the whole EU. Customers using our sectors' products without alternatives count up to thousands. d: Even after over 10 years of working on alternatives we have not found or developped a working alternative e: Working together with producers in other sectors that make products that could work for our belts. Also working in our R&D dept together with customers. Time never kept, but multiple employees over many years. f: Unknown. g: Unknown. Our company has over 50 employees and over 7M EU sales Answer to specific info request 8:
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3898	Date: 2023/04/17 16:25 Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Switzerland Company name confidential: Yes Attachment: [REDACTED] Privacy statement: Protection of our commercial interests, including intellectual property, would be undermined by publication	Answer to specific info request 6: See confidential attachment
		Answer to specific info request 8: See confidential attachment

3899	Date: 2023/04/17 18:47 Content:	General Comments: Dear Sirs, we are a Company that produce PTFE compounds, micropowders for additivities and post-treat PTFE suspension. We comment the Annex XV because we support the fact that PTFE cannot be considered and regulated in the same way than the short chain PFAS, because it is not dangerous and
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	Hazard or exposure Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Italy Company name confidential: Yes	cannot be replaced in majority of the actual applications. The peculiar properties of chemical inertia, thermal resistance and friction, are for PTFE both the advantage and the problem because it is no toxic or dangerous for health , resistant to hard environment and working conditions, but at the same time it is persistent in the environment. We support the fact that a good end of life management of the polymer is the most efficient compromise to take advantage from the opportunities of use of this particular PFAS. We have no direct contact with final manufacturers, so we have no access to data referred to the single application. Our contribute can be evidence in socio economic impact that the PTFE ban could have in our area. Our company is specialized in PTFE compounding, PTFE micropowder and industrial PTFE turnings recycle (Reprocessed Material), we collect those from our customers and after treatment it is possible to reuse for some applications. There is no possibility to convert the whole machinery used in POLIS for the PTFE treatment in different processes, so the only chance in case of PTFE ban, is to close the activity. The social economic impact will involve: <table border="1"> <thead> <tr> <th>Product</th><th>Volume sold (2022)</th><th>Volume loss (total ban of PTFE)</th></tr> </thead> <tbody> <tr> <td>PTFE</td><td>1000-2000 t/y</td><td>100% loss</td></tr> <tr> <td>PTFE compound</td><td>2000-3000 t/y</td><td>100% loss</td></tr> <tr> <td>PTFE micropowder</td><td>500-1000 t/y</td><td>100% loss</td></tr> <tr> <td>PTFE reprocessed (by industrial turnings)</td><td>500-1000 t/y</td><td>100% loss</td></tr> </tbody> </table> Number of workers involved (people) : 160 Number of redundancy (total ban of PTFE) :160 Polis market share will be completely absorbed by non EEA companies that will produce in non EEA country. Answer to specific info request 1: Food contact material and packaging, Cosmetic, Medical device, Transport, Electronics and semiconductor, Energy sector, Lubricant, Petroleum and mining are all fields where PTFE post-treated by Polis is used. Other involved sectors are CPI, Pharmaceutical , Industrial gaskets and bearing.	Product	Volume sold (2022)	Volume loss (total ban of PTFE)	PTFE	1000-2000 t/y	100% loss	PTFE compound	2000-3000 t/y	100% loss	PTFE micropowder	500-1000 t/y	100% loss	PTFE reprocessed (by industrial turnings)	500-1000 t/y	100% loss
Product	Volume sold (2022)	Volume loss (total ban of PTFE)															
PTFE	1000-2000 t/y	100% loss															
PTFE compound	2000-3000 t/y	100% loss															
PTFE micropowder	500-1000 t/y	100% loss															
PTFE reprocessed (by industrial turnings)	500-1000 t/y	100% loss															

3900	Date:	General Comments:
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2023/04/18 07:58 Content: Hazard or exposure Environmental emissions Information on alternatives Other socio economic analysis (SEA) issues Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Germany Company name confidential: Yes	Used material PFA Type 6505TZ (Dyneon), Type 6515 TZ (Dyneon), Type 6502TZ (Dyneon), Type 8003 (INOFLON), Type 8015 (INOFLON), Type 8003 HS (INOFLON), Type 8015HS (INOFLON) CLP Regulation No. 1272/2008 Not classified as a hazardous substance CAS-number: 26655-00-5 No hazard or exposure due to the material PFA No environmental emissions due to the material PFA: No equivalent alternatives for the pump material type PFA in the applications: pharmaceutical precursors, green hydrogen production, food precursors, pumping of dangerous acids, alkalis and chemical wastewater. Pumps in these applications must be chemically sterilizable and have to have a high resistance to the sterilization agents. Highly fluorinated sealing materials: There are alternatives for the sealing materials FPM, FFPM and TFM to avoid dangerous exposure of the pumped media. These materials are required because of their high resistance to critical and dangerous media. Socio-economic impacts: If these materials are banned, the consequences are as follows: health and environmental hazards. Significant technological step backwards in the manufacture of the aforementioned products. Socio-economic impacts: If these materials are banned, the consequences are as follows: health and environmental hazards. Significant technological step backwards in the manufacture of the aforementioned products. Reduction of quality of life due to technological limitations in the aforementioned areas. Reduction of electromobility. Increased dependency on a few Asian trading partners in the semiconductor industry. No listing in Annex XV of the REACH regulation Request for exemption: We apply for the exclusion of the substances mentioned (Fluoropolymers and highly fluorinated sealing materials) from the PFAS ban.
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3901	Date: 2023/04/18 08:03 Content: Hazard or exposure Environmental emissions Information on alternatives Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Germany	General Comments: Used material PVDF: Type Polytetraflon® PTFE No risk or exposure due to the material PTFE No environmental emissions due to the material PTFE No equivalent alternatives for the pump material PTFE in the application of chlorine electrolysis. EC number PVDF: CLP Regulation No. 1272/2008 Not classified as a hazardous substance CAS-number 24937-79-9 Highly fluorinated sealing materials: There are alternatives for the sealing materials FPM, FFPM and TFM to avoid dangerous exposure of the pumped media. These materials are required because of their high resistance to critical and dangerous media. Socio-economic impacts: If these materials are banned, the consequences are as follows: health and environmental hazards. Significant technological step backwards in the manufacture of the aforementioned products. Reduction of quality of life due to technological limitations in the aforementioned areas. Reduction of electromobility. Increased dependency on a few Asian trading partners in the semiconductor industry. No listing in Annex XV of the REACH regulation
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	Company name confidential: Yes	Request for exemption: We apply for the exclusion of the substances mentioned (Fluoropolymers and highly fluorinated sealing materials) from the PFAS ban.
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3902	Date: 2023/04/18 08:08 Content: Hazard or exposure Environmental emissions Information on alternatives Other socio economic analysis (SEA) issues Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: 	General Comments: Used material PVDF: Type Solef 6012 (Solvay), Type Solef 1008 (Solvay) No hazard or exposure due to the material PVDF No environmental emissions due to the material PVDF No alternatives for the pump material PVDF in the applications: pharmaceutical precursors, food precursors, pumping of dangerous acids, alkalis and chemical waste water, battery recycling, fertilizer production . Chlorine electrolysis. Pumping of ultrapure water for semiconductor and microchip production. EC number PVDF: CLP Regulation No. 1272/2008 Not classified as a hazardous substance CAS-number 24937-79-9 Highly fluorinated sealing materials: There are alternatives for the sealing materials FPM, FFPM and TFM to avoid dangerous exposure of the pumped media. These materials are required because of their high resistance to critical and dangerous media. Socio-economic impacts: If these materials are banned, the consequences are as follows: health and environmental hazards. Significant technological step backwards in the manufacture of the aforementioned products. Reduction of quality of life due to technological limitations in the aforementioned areas. Reduction of electromobility. Increased dependency on a few Asian trading partners in the semiconductor industry.
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	Org. country: Germany Company name confidential: Yes	No listing in Annex XV of the REACH regulation Request for exemption: We apply for the exclusion of the substances mentioned (Fluoropolymers and highly fluorinated sealing materials) from the PFAS ban.
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3903	Date: 2023/04/18 08:11 Content: Hazard or exposure Environmental emissions Information on alternatives Other socio economic analysis (SEA) issues Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name:	General Comments: Used material PTFE: PTFE: Type Polytetraflon® PTFE No risk or exposure due to the material PTFE No environmental emissions due to the material PTFE No equivalent alternatives for the pump material PTFE in the application of chlorine electrolysis. EC number PTFE: CLP Regulation No. 1272/2008 Not classified as a hazardous substance CAS-number: 9002-84-0 Highly fluorinated sealing materials: There are alternatives for the sealing materials FPM, FFPM and TFM to avoid dangerous exposure of the pumped media. These materials are required because of their high resistance to critical and dangerous media. Socio-economic impacts: If these materials are banned, the consequences are as follows: health and environmental hazards. Significant technological step backwards in the manufacture of the aforementioned products. Reduction of quality of life due to technological limitations in the aforementioned areas. Reduction of electromobility. Increased dependency on a few Asian trading partners in the semiconductor industry.
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	Org. country: Germany Company name confidential: Yes	No listing in Annex XV of the REACH regulation Request for exemption: We apply for the exclusion of the substances mentioned (Fluoropolymers and highly fluorinated sealing materials) from the PFAS ban.
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3904	Date: 2023/04/18 08:26 Content: Scope or restriction option analysis Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Germany	Answer to specific info request 1: Wir benötigen zur statischen als auch dynamischen Abdichtung in Gleitringdichtungen O-Ringe.
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	Company name confidential: Yes	
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3905	Date: 2023/04/18 11:14 Content: Environmental emissions Baseline Type: Individual Country: Germany	General Comments: OK
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3906	Date: 2023/04/18 11:27 Content: Hazard or exposure Environmental emissions Baseline Information on alternatives Information on benefits Request for exemption	General Comments: As a manufacturer of rubberised roller covers with an additional PFA or FEP coating in the form of an extruded semi-finished product as a functional layer Down Stream User), we primarily supply companies in the liquid packaging industry. The covers we produce are directly and immediately required for the production of food packaging materials and cannot be substituted. When used as intended, no hazards are to be assumed. FEP and PFA and ETFE are known as "polymers of low concern"(PLC) as defined by the OECD. They are not high risk materials as they are not water soluble, not bioavailable or bioaccumulative, inert, stable and non-toxic and do not contain harmful PFAS materials. Furthermore, due to their inertness, our coatings are specifically used in the medical care sector and are not substitutable.
		Answer to specific info request 6:

	Type: BehalfOfAnOrganisation Org. type: Company Org. name: Ahauser Gummiwalzen Lammers GmbH & Co. KG Org. country: Germany	a: No data b: Unknown, since semi-finished product c: 136 d: No alternatives because of the required combination of chemical inertness, adhesive behaviour, chemical resistance, e: In the field of aseptic liquid packaging production due to the wetting and polar displacement of the acid co-polymers to be coated by adhesion promoting measures which are indispensable (corona, ozone, flame treatment), no substitute has been found in the entire rubber coating industry for about 25 years. f: no information g: loss of 30% of jobs in our company. The damage to consumers caused by the loss of almost all liquid packaging systems cannot be quantified if PFA, FEP and ETFE are banned. For the global manufacturers of liquid packaging, a ban means a complete inability to act due to a lack of alternatives to PFA/FEP coated rollers or PTFE belts, seals, etc.. In this sector alone, we are talking about trillions of packaging units/year and >100,000 jobs worldwide, which would endanger the global supply of packaging for food.
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3907	Date: 2023/04/18 13:44 Content: Scope or restriction option analysis Hazard or exposure Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption Type:	General Comments: Please refer to attached document "Section III Submission.pdf"
		Answer to specific info request 1: Specifically, we are commenting on the semiconductors, petroleum and mining sectors. In considering the possible replacement of PFAS by substitutes or alternatives as a response to any risk management action, it is necessary to consider their technical suitability, cost (economic feasibility), environmental and human health effects, as well as their capability to meet relevant required performance standards. For fluoropolymers and fluoroelastomers, the industry view appears to be that for many or most uses there are no alternatives with the requisite performance characteristics. PTFE / PFA fluoropolymer lined pipework and associated equipment are deployed on a global basis, safely transporting various liquids and liquified gases in bulk around a huge variety of manufacturing and processing sites, most of which are classified as dangerous goods or are otherwise potentially hazardous. These highly regulated industries, rely upon the PTFE / PFA fluoropolymer lined pipework and associated equipment to withstand extreme conditions in terms of corrosion and temperature as well as being versatile enough to be capable of handling many different types of media as processes change. PTFE / PFA fluoropolymer lined pipework and associated equipment must provide a range of technical properties that ensure the materials function as reliable and safe containment the respective chemicals. Fluoropolymer, materials such as PFA and PTFE, are widely used because of the proven properties of chemical resistance,

BehalfOfAnOrganisation Org. type: Company Org. name: Corrosion Resistant Products Ltd Org. country: United Kingdom Attachment: ref_3907_public.zip	temperature range, durability and vibration resistance. The exceptional properties of these lined pipe and associated equipment significantly impact on the operational safety and leak tightness record of the chemical process industry. Alternative lining element materials have been researched and in some controlled applications have been trialled but there is an overwhelming technical need to continue the use of fluoropolymers. There is a risk to the environment and the public should access to the totally reliable existing pipe lining element material be restricted. The material in this form does not shred or degrade into particles. Sealing elements have a long-life expectancy and are eventually safely disposed of as licensed industrial waste. Several trade bodies and associations have initiated a variety of programs to consolidate used materials and to seek recycling options. The safe containment and minimised contamination of chemicals is the prime consideration of the user of PTFE / PFA fluoropolymer lined pipework and associated equipment. This requires the use of lining and sealing elements with a critical range of properties and attributes. Essential operational properties of these materials include: • Chemical resistance and compatibility • Thermal stability • Durability Chemical resistance and compatibility Process and manufacturing industries use a wide range of chemicals which require the lining and sealing elements to be compatible over the range. This is achieved by currently the use of PTFE / PFA fluoropolymer lined pipework and associated equipment. Whereas some processes are dedicated to a specific chemical at a specific temperature, most are designed to be 'flexible' in their design to handle different substances according to production demand. The cost of labour, materials, and downtime to change pipework and associated equipment before each process change, should the current universally compatible lining and sealing elements not be available due to regulatory restriction, would be prohibitive. Furthermore, the need to change contaminated lining and sealing elements would result in an added safety risk to maintenance personnel and increased waste disposal. Thermal stability PTFE / PFA fluoropolymer lined pipework and associated equipment are manufactured to meet the general industrial required temperature range of -40°C to +200°C. These lining and sealing elements must therefore equally perform at these temperatures. Even if operating at ambient temperatures, certain corrosive chemicals are incompatible with alternatives fluoropolymer lined pipework and associated equipment. Furthermore, it is possible that such installations must be able to withstand high pressure water and cleaning fluid temperatures of up to 95°C and steam of about 160°C during the decontamination process. Some process and manufacturing industries require these chemicals to circulate at a variety of concentrations, temperatures and pressures depending on the role they are fulfilling which again calls for a versatile solution that currently only PTFE / PFA fluoropolymer lined pipework and associated equipment can provide. Durability Lining and sealing elements must be hard-wearing and be capable of withstanding a degree of handling damage as well as movement between different components. In addition, lining and sealing materials should not absorb the substances they transport. During maintenance programmes, absorbed substances which are often dangerous goods, are
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	a safety risk to personnel undertaking works. In the manufacturing and process industries, chemicals are transported over relatively long distances, at height, often in difficult to reach areas of a factory and as such have limited access for frequent inspection. Lining and sealing elements once installed and tightened to the specified torque, must remain reliably leak tight. This means that the material properties are required to resist any compressive set which would allow vibratory forces to act on the fixings and consequently risk leakage. Semiconductor Sectors. As semiconductors become more complex, they require increasingly higher purity of etching acids (36x10⁻¹² or 36 parts per trillion) in the manufacturing process. Consequently, metallic equipment cannot be used as wetted materials in this process hence lined pipe and equipment is necessary. At present ONLY PTFE or PFA lined products can provide the necessary characteristics required in terms of temperature (150°C) and corrosion resisting performance for these duties. Given the importance of this industry and the rate of its development, a ban or even a 12-year derogation would jeopardise the semiconductor manufacturing industry substantially. Petroleum and Mining Sectors. Again, the refining and transportation of petrochemicals and mining solutions require the use of chemicals that are incompatible with the majority of lined and unlined pipework. As in the semiconductor sector, currently there are no alternatives to PTFE/PFA lined pipework that can tolerate the varieties of substances, their varied concentrations and operating temperatures. At present it is unclear whether technically and economically feasible alternatives to PTFE / PFA fluoropolymers can be developed within a 12-year timescale. Answer to specific info request 2: It follows that the benefit of existing PTFE / PFA fluoropolymer lined pipework and associated equipment, which have a long-life expectancy and wide chemical compatibility, is that it reduces the frequency of pipe and valve element maintenance and replacement and therefore the quantity of items manufactured per annum and the quantity disposed. New material from manufacturing off-cuts and machining and drillings can be recycled. Used material recycling is currently problematic. However, some companies have developed methods for recycling PTFE. PTFE and PFA can be broken down into its constituent monomers, which can then be used to create new PTFE, PFA or other fluoropolymer materials. Another approach involves grinding PFA into a fine powder, which can be used as a filler in other materials. While these recycling methods are still in their early stages, they show promise for reducing the environmental impact of PTFE production and waste. Answer to specific info request 3: Incineration involves burning the PTFE / PFA fluoropolymers at high temperatures in the presence of oxygen, which breaks down the polymer into its constituent elements. However, it's important to note that incineration of PTFE can release toxic gases such as hydrofluoric acid and other hazardous air
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		pollutants. Therefore, it's essential that PTFE / PFA fluoropolymers are incinerated in specialized facilities that are designed to safely handle hazardous waste. These facilities are equipped with advanced air pollution control technologies, such as scrubbers and filters, to capture and treat the toxic gases released during the incineration process. Overall, incineration of PTFE / PFA fluoropolymers can be a safe and effective way to dispose of the material when done in a controlled manner in specialized facilities that are equipped to handle hazardous waste with the heat created used to generate electrical energy.
		Answer to specific info request 6: Please refer to attached document "Specific Information Requests. 6 Missing Uses Submission.pdf"

3908	Date: 2023/04/18 15:57 Content: Information on alternatives Transitional period Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Germany Company name confidential:	General Comments: Sehr geehrte Damen und Herren, bei einem PFAS-Verbot wie es aktuell geplant ist, könnten wir im Bereich der Dichtungstechnik, und im speziellen der Gleitringdichtung auf dem Weltmarkt nicht mehr bestehen. Durch ein Verbot würde Herstellung in den asiatischen Raum verlegt werden. Viele unserer Kunden sind in Asien. Jedoch wird Stand heute zu 100 % in Deutschland produziert. Mit dem PFAS-Verbot in der jetzigen Form würden die Produkte schon sehr zeitnah in Asien hergestellt werden. Auch die sehr kurze Übergangszeit wird das abwandern der Produktion beschleunigen.
		Answer to specific info request 1: Unsere Produkte (Gleitringdichtungen und Rührwerke) kommen in den Bereichen Mining, Pharma, Food, Kunststoff, Chemie (eigentlich überall wo gerührt werden muss) zum Einsatz.
		Answer to specific info request 3: Die Verwendeten Produkte/Bauteile werden durch die Betreiber nach dem Austausch fachgerecht Entsorgt/Recycelt.
		Answer to specific info request 6: Mithilfe von Fluorpolymeren gelingt es Rührbehälter gegenüber der Atmosphäre abzudichten.

	Yes	
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3909	Date: 2023/04/19 05:14	General Comments: Fluoroelastomers are the only elastomers that can withstand temperatures above 200°C and have almost no volatility. Silicone rubber cannot be used at temperatures above 200°C for long periods of time, and its volatile components can cause insulation problems in electronic components.
	Content: Information on benefits	Answer to specific info request 1: Currently, VMQ is the main basic material for TIM(Thermal Interface Material), but its heat resistance is limited, and in the case of electronic components, there is an insulation problem due to volatile components; as SIC semiconductors and other devices will generate more heat every day, FKM (fluoroelastomers) with higher heat resistance and almost no volatility will become indispensable. There is no alternative to FKM.
	Type: BehalfOfAnOrganisation	Answer to specific info request 4: FKM-based TIM material can be separated and made into powder particles for use as a fluoropolymer modifier. The modified fluoropolymers can be used as high-performance electronic substrates. It can also be recycled as a thermoplastic elastomer, and due to the thermal stability of fluoropolymers, it can be recycled many times.
	Org. type: Company	Answer to specific info request 5: This use should be exempt from regulation. The use of TIM is not in direct human contact and is far less volatile than other materials.
	Org. name: Tokyo Zairyo Co.,Ltd, Org. country: Japan Attachment:  ref_3909_public.pdf	Answer to specific info request 6: There is no alternative material due to the high temperatures at which neither silicone nor EPDM can be used. Fluoroelastomer is non-toxic.

3910	Date: 2023/04/19 11:30	General Comments: The proposal include some derogations that preferably would require strict definitions to avoid ambiguity and potential loop holes. We have identified the following unclarities:
	Content:	• Transport refrigeration – and specifically if this sub-use would include all type of transports on land, on

Scope or restriction option analysis Environmental emissions Baseline Information on alternatives Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Dometic Org. country: Sweden Attachment:  ref_3910_public.pdf	sea and in air, and if there is any limitation on what type of good is transported and refrigerated. • Mobile Air-conditioning - and specifically if this sub-use is equal to products within the scope of the MAC-Directive or if any other mobile air conditioners would fall under the proposed derogation. • Mobile – and specifically if this would have the same understanding as in the F-gas Regulation: “normally in transit during operation” We appreciate if clear definition could be included in the legislation and furthermore that such definitions are fully aligned with those found in other relevant legislation covering products in scope. Answer to specific info request 1: Our comments is applicable for the following sectors and (sub-) uses: • Applications of fluorinated gases including the sub-uses Refrigeration and Air conditioning and heat pumps • Transport including the sub-use HVACR- systems Answer to specific info request 2: a) For all type of equipment provided by Dometic (examples with some product information is listed in Annex B of the attached public information), extended product responsibility applies and is outlined in the WEEE and ELV directives depending on the product applications. Both these directives prescribe a full reclaim of refrigerants at end-of-life. As provider of products we are participating in the relevant recycling systems and provide end-of-life operators with relevant product information. The actual performance level of the end-of-life collection n and treatment is however, out of our control. We would not like to make any assumptions but encourage you to take direct contact with operators in the end-of-life chain for more information. Emissions of PFAS refrigerants might also appear in small quantities during product manufacturing and during the use-phase of products (accidental leaks). We will come back to you later in this consultation with more details on these emission as confidential information after consulting internal sources. b) Refrigerants reclaimed at end-of-life should be incinerated at high temperature to decompose the molecules. The actual performance level for these steps is out of our control and we have no further information. Answer to specific info request 5: Dometic is not affected by the proposed derogation and consequently we have no information to share here. Information under our requested derogation is found under Q6. Answer to specific info request 6: We don't see that the use of refrigerant for several mobile and portable application of refrigeration and
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		air-conditioning - other than transport refrigeration and car air-conditioning - have been assessed in the proposal. With reference to details below, we therefore request a new derogation with the following suggested wording: “Refrigerants for refrigeration and air-conditioning in recreational vehicles, trucks, boats and passenger cars (with the exemption of those within the scope of Directive 2006/40/EC of the European Parliament and of the Council), and in portable cooling boxes, until 6.5 years after EiF”. This sub-use may be sorted in under the use sector “Applications of fluorinated gases” or under “Transport” For this use we respond on the detailed questions as follows: a) On the tonnage and emissions: The main PFAS refrigerants for this use are R134a, R1234yf and the blends R410A, R407C, R417A and R404A. We would like to respond to you in a later stage on the tonnage and an estimation for the emissions at manufacturing and use phase related to products placed on the EU market. However, we would already now like to comment that for this use the concerned products on the EU market are covered by extended producer responsibility according to the WEEE Directive or the ELV Directive. Following these directives, any refrigerants must be reclaimed and treated separately at end-of-life. The actual performance level of the collection and end-of-life treatment facilities is however not within our control. For emissions during production and from leaks during the use phase we will come back to you with more accurate figures later in the consultation. b) On type of PFAS: PFAS is present as refrigerant for this use. c) On the market: This use include a wide range of different products and also many different providers for individual products. Some sub-uses are dominated by import from many small providers. Dometic is the major provider of this type of product on the EU market. To give you a better understanding of the market situation we will provide you with more confidential details later during the consultation. d) On alternatives in general: Because of the diversity of products and applications for this use, the alternatives to PFAS refrigerants also vary significantly. Furthermore, the legal situation is different for different markets, an important aspect for us as a global provider of products. We see mainly flammable hydrocarbons (R600a and R290a) – classified as A3 refrigerants - as alternatives for the smaller hermetically sealed products, and potentially CO2 for bigger ones. R32 could technically be an alternative for air-conditioning applications but will not meet the GWP threshold of the new F-gas Regulation. The alternatives present different challenges. For the hydrocarbons this is mainly the safety concerns and the need for a deep safety assessment. Leaking refrigerants could be ignited with risk of fire and explosion. For CO2 the bottleneck is the availability of components, but also the challenges related to the very high pressure. We will elaborate on the alternatives more in detail under question 6d and 6e below. Dometic is already in the process of analyzing the introduction of alternative refrigerants for its products. Some products, with limited safety hazard, is already in the process to be implemented on the market converted to new refrigerants. This include some refrigerators with small refrigerant charge aimed for larger recreational vehicles (RV) and minibars to cruise line ships. We have also notices that some competitor have introduced some products for RV containing hydrocarbon refrigerants on the
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		EU market. For most of the products though, the conversion is still in a planning phase. e) On alternatives not yet available: We consider CO2 to be a potential future alternative for some of our larger chillers and air-conditioning units mainly for marine applications. Existing products operate on the blends such as R410A and R407C. We don't see conversion to flammable A3 refrigerants being an option for these products because of the big refrigerant charge in combination with boat installations. Potential leaks in boats are critical and could cause both explosions and fires. In marine application also a small fire could cause a major accident with limited, or no, escape options. The major challenge with CO2 in our applications is the availability of components, specifically compressors, in suitable sizes for our applications. Furthermore, CO2 require a significantly higher system pressure that both possesses safety risks and risk of lost performance because of the high input power needed. The higher system pressure will also increase weight of the components. A lower efficiency and a higher weight will inadvertently increase the energy consumption which is very unattractive from a climate perspective. No compressors for Direct Current (DC), required in mobile application, are available today for CO2. Dometic has not started any activities related to CO2 as refrigerant more than theoretical studies. We estimate that the development process will take minimum 5-8 years assuming that the component developments continue to progress. f) On alternatives where substitution is technically and economically feasible but more time is required: For most of the hermetically sealed products our plan is to move to flammable hydrocarbon refrigerants. Technically we know that this is feasible and the availability of components is good. However we have strong concerns on the safety aspects related to risks of igniting leaked refrigerants. Important considerations here are: 1. The products are often installed in confined spaces like small vehicle and marine application where also leakage of a limited refrigerant charge could present a significant risk. Air-conditioning units for trucks is one type of products that we identified as critical. We as a product provider do not fully control how the products is installed, used and stored, and information in manuals is often not followed by the user. 2. Portable products, like cooling boxes, are by definition flexible and could be stored and used in many confined spaces, like wardrobes, in small boats or in the car trunk. The free volume in these places is often too small to dilute a leaked refrigerant charge and consequently a spark could ignite the refrigerant with severe consequences. 3. Mobile devices are per definition subject to significantly more vibration than stationary refrigerators, freezers, air conditioners and other appliances due to intended use. Therefore the risk of leakage is also higher for mobile products. To reduce the risks several options exist like minimizing the refrigerant charge, elimination of components with sparks, minimize tube joints (risk of leakage), sensors to detect leaks etc. Furthermore, simulations and real test could be used to understand the concentration levels of refrigerant at leak condition in the installation. Fault tree analyses is a tool we use to assess the risk associated with leaked refrigerants. Products safety standards consider safety aspects on flammable refrigerants and has shown to be a powerful tool to design safe products. However, safety standards for
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		refrigeration products do not consider the safety aspect related to the environment where the products are used or stored. As mobile and portable products have a different use case than domestic products we have identified this as a potential risk. The overall most critical bottleneck for us is related to the development time, because of the huge number of products that need redesign and safety assessment. The example products provided in Annex B of the attached document show some major product categories. These in turn are spitted on many individual models families, models and stock keeping units (SKU). We estimate that approximately 240 different models and 890 SKU's must be converted to new refrigerant. i) It is at this stage difficult to predict detailed costs associated with the substitution, but generally speaking cost will appear both in relation to products (development costs, additional safety components, certification, extended safety assessments, field tests), manufacturing sites (new installations, safety monitoring systems, training) on the market (training, marketing material) and at end-of-life. Cost for product development is depending on the number of products (models) that should be converted. We could provide you with a cost estimate in a later stage of this consultation as confidential information. ii) Time to re-design products and fully implement new refrigerants vary significantly between product categories. We estimate that most of our products could be converted in the time frame of 3-6 years depending on complexity and the number of models that must be converted. It can however not be ruled out that our risk assessment for some products will come to the conclusion that flammable refrigerants are not possible to introduce. iii) We do not see that new refrigerants should affect the product performance or life time significantly. Slightly increased energy consumption could not be excluded for some products because of safety monitoring systems. Due to safety concerns we might also need to limit the approved use for some products. We however foresee that the product price will increase because of increased safety measures such as sealed electrical components and systems to monitor leaks. We estimate that these additional costs will be in the area of 10-20% increase. g) We are not yet in a position to determine if the transition to non-PFAS refrigerants will be successful on all products in our range, and therefore it is difficult to make any assumptions. In the event the transition will fail because of safety aspects, technical or economic reasons, concerned products have certainly to be phased out from the EU market, but not necessarily from other markets. Our manufacturing is split on EU and non-EU, and similar products produced in EU are sold on many markets. Products not conforming to the new requirements, and sold to non-EU markets, must therefore be produced outside EU if we would like to keep them available. We have so far not elaborated with figures on potential loss of job opportunities, or economic consequences, for these events.
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3911	Date:	General Comments:
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2023/04/19 11:54 Content: Scope or restriction option analysis Information on benefits Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Germany Company name confidential: Yes Attachment: ██████████	We therefore apply for a general derogation of measuring and process devices, which can't be substituted within a short time frame (less than 10 years). A limitation to special applications or industries is not feasible, due to numerous uses at our customers. A short time substitution with the currently on the market available alternatives, will result in a shorter lifetime and limited specification of the devices. With this, prices of the manufactured products with the devices will increase or cause shortages for consumer products and critical materials like petrol or pharmaceuticals. Nevertheless, a broad restriction of applications and materials in the EU, will have a massive impact on the business of European companies and may result in shifting of R&D and manufacturing sites. Employees will be blocked with redesign instead of innovation. With this, the strength and attractiveness of Europe will decrease and result in a loss of employees and disadvantage in a global value chain. Answer to specific info request 1: Measurement devices (for flow, pressure, temperature, level, analytical parameter, ...) are used in various applications of process industries (e.g. chemical industry, food&beverage, pharmaceutical industries, life sciences, oil&gas, mineral&mining, ...) and have to follow standards (IEC, GMP, CSA, ASME, EHEDG, Ex...) which require tests and approvals of instruments according these standards. To substitute a part containing PFAS, a redesign of an instrument including a requalification of the usability in the application is necessary. The time period needed for a redesign of a product is much longer than the suggested transitional period of 18 months. More details can be found in the attached document. Answer to specific info request 6: (a) For tonnages and further detailed information see confidential attachment (b) The PFAS in these application (e.g. PFA, PTFE and others) are mostly used because of their resistance against temperature and strong chemicals and the unique combination of both. Also, they provide the needed good isolating characteristic, the non-stick property and a significant longer lifetime than the existing alternatives for limited, selected applications. (c) To our current knowledge, we estimate at least more than 100 companies in process operation and surveillance will be affected. (d) The described characteristics result in a much more durable and longer lifetime (e.g. 15 instead of 5 years), which reduces costs for the user of the devices, as well as for the end-user. With a shorter lifetime of alternative materials used in the devices and a resulting more often change of the devices, the price level for the manufactured consumer products will increase and bring a less sustainable way of production with much more waste, through changing the electronic devices regularly. The available materials with their current tonnages on the market, will lead to supply shortages, especially for smaller companies. With the ramp-up and qualification of new materials, the R&D process can easily take up to 10 years and more, also see
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		attachment. (e/f/g) see confidential attachment
		Answer to specific info request 8: measurement products (for flow, pressure, temperature, level, analytical parameter, ...) used in various applications of process industries and labs (e.g. chemical industry, food&beverage, pharmacycital industries, oil&gas,...)

3912	Date: 2023/04/19 15:04 Content: Hazard or exposure Information on alternatives Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: ██████████ Org. country: Germany Company name confidential: Yes	General Comments: COG is a manufacturer of elastomer seals with specialised expertise in the field of fluorine-containing polymers. These polymers are used worldwide in demanding applications, for example, in medical technology, the food and pharmaceutical industries, and also in the energy sector (hydrogen, electrolysis, photovoltaics, wind energy, etc.), in semiconductor production and generally in mechanical engineering. Either no or only considerably inferior alternatives exist for these applications. For example, high-purity FFKM polymers are used for sealing in the semiconductor industry (wafer/chip production). Alternative materials for these applications do not exist at this time. The same applies to many production facilities in the pharmaceuticals industry. For example, the very purest water (WFI=water for injection) is used here in production so that medications and pharmaceutical products such as insulin of high purity can be produced. In addition to media resistance to WFI and the product, the special FKM material used here features a low migration rate that cannot be matched by any fluorine-free alternative material in this combination. A general PFAS ban would cause tremendous problems in other segments of the pharmaceuticals industry as well, because alternative materials do not come anywhere close to current service lives. For example, a production facility that currently has a service life of 250 hours could only operated for approximately 90 hours with an alternative material. Production costs would therefore rise significantly due to increased seal wear and additional production stops. Safe alternative elastomer materials for many sealing applications currently do not exist in medical technology or the food industry either. The problem is further exacerbated by the approvals required for pharmaceuticals and the food industry (FDA, USP, ISO 10993, 3-A Sanitary, etc.). While these approvals can be obtained for alternative materials that can be considered from a technical perspective, they do not meet the necessary application criteria such as WFI resistance. A general ban on PFAS for polymers in the sealing technology field would set the technology back by decades and endanger the safety of products and applications. The climate goals set by the EU and Germany for renewable energy can only be realised on the basis of fluorine-containing polymers.
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	Attachment: Privacy statement: protection of commercial interests	Furthermore, the (per)fluorinated rubber material group sets itself apart with high temperature resistance. Alternatives in the corresponding temperature ranges do not exist at this time. This is made clear in particular by the ASTM D2000 chart on page 64 of the attached PDF file. The temperature range covered by fluorinated compounds is coloured blue, notably in reference to high temperatures. This diagram shows that only fluorine-containing sealing materials exhibit a corresponding high thermal stability. They are compared here to other typical sealing materials that are not fluorine-based. VMQ materials are not a suitable alternative since they cannot be used in certain fields because of resistance to media. The table on page 63 of the attached PDF file present the common acids: sulphuric acid, hydrofluoric acid and nitric acid. Here the perfluorinated material FFKM is compared to the typical non-fluorinated sealing materials. This clearly shows that only a fluorinated material (FFKM in this case) can be used in applications with the acids in question. Reliable sealing for these chemicals, ensuring that they cannot escape into the environment, requires the use of this material. An undifferentiated PFAS ban would not only have serious negative economic consequences for COG, but could threaten the company's existence. As of 2021/2022, materials based on fluoropolymers (FKM, FFKM, FEPM, FVMQ) account for more than 62% of the company's sales. If these sales were to be eliminated by a general PFAS ban, only a small proportion could be made up by other materials such as HNBR or VMQ. There are no alternatives to FKM and especially to FFKM sealing materials. COG would have to dismiss at least 150 employees out of its current staff totalling nearly 300. Since fixed costs based on existing sales budgets cannot be eliminated, the PFAS ban could also threaten the company's existence because generating sufficient compensating sales quickly is not possible. Answer to specific info request 1: Food contact materials and packaging (Annex E.2.3.): Subuse: Industrial food and feed production Differentiating between polymers and non-polymers in the PFAS context is absolutely essential and meaningful: Fluoroelastomers are considered non-toxic, not bioavailable, not water-soluble and non-mobile. The OECD (Organisation for Economic Co-operation and Development) defines criteria for "polymers of low concern", summarised as follows: Fluoropolymers that meet the OECD criteria for "polymers of low concern" have insignificant environmental and human health impacts. The stability of fluoropolymers results in unique and lasting performance in many uses and applications. Furthermore, the unique durability of fluoropolymers makes them ideal materials to enable innovations.
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		Fluoropolymers should be exempted from all regulatory measures within the scope of the REACH restrictions. In the pharmaceuticals sector, this good compatibility is proven by test reports (USP <87>, ISO 10993-5 and <88> as well as 10993-4 found in the appendix pages 4 to 62). Examples of tests that were performed include cytotoxicity, material implantations under the skin and compatibility tests with blood (haemolysis test). FKM performed very well in all these respects. Furthermore, many fluoroelastomers have been approved for food applications after testing (FDA). The FDA approvals for two polymers (Viton GF200S and Aflas 100S) are found in the appendix pages 1 to 3.
		Answer to specific info request 5: We produced 70 tons of FKM in 2022.

3913	Date: 2023/04/19 18:05 Content: Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: AP-Miniplant GmbH & Co. KG Org. country: Germany Privacy statement:	General Comments: We are a manufacturer of scientific test plants for the process industries and renewable energies. We use components containing such substances mainly for sealing and piping material. Especially for the sealing and for the piping of highly aggressive substances we have no alternatives. Currently you would find these materials in 100 % of our individually manufactured research plants. Without the availability of such products we are currently not able to continue our business.
		Answer to specific info request 1: Manufacture of metal products not addressed elsewhere, PTFE thread sealing tape Fluoropolymer applications Energy Sector - PEM membranes
		Answer to specific info request 2: When we deliver a system, we instruct the user to use the recycle paths given when decommissioning our units. We do not know if this actually happens. We know that components as a whole are reused for other purposes. But since our customers know the components and are experts in chemistry, it should be relatively easy to recycle or professionally deposit the material.
		Answer to specific info request 3: As mentioned before, we think that in our field it is possible to responsibly deposit the components in our units.
		Answer to specific info request 5:

	for a better understanding of our products, see www.miniplant.de	We are using such materials in small amounts, mostly less than 10 kg per year. There is no emission from our side and very little emission during the lifetime of our units. That is why we think an exception is necessary for research purposes or better generally for chemical production plants.
		Answer to specific info request 6: We use mainly sealing material like PTFE, FKM, FFKM, PFA, FEP, PVDF. In a few cases we can replace them by other plastic products such as EPDM, NBR, PA, PP, PE or Silicone. But in most cases chemical resistance or temperature problems force us to use fluor-polymer products. Without these it is not possible to build our systems.
		Answer to specific info request 7: We do not see chemical resistant alternatives on the market by now. To develop new material alternatives, for example our units are needed. And these units can only be built with such materials, as long as no alternatives are available. If we do not have it, we have to stop our business activities.
		Answer to specific info request 8: Manufacture of metal products not addressed elsewhere, PTFE thread sealing tape, Fluoropolymer applications: See above, we do not have alternatives Energy sector - PEM membranes: No information on this topic.

3914	Date: 2023/04/20 10:03 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: Individual Country:	General Comments: The materials concerned are essential for the industry, especially for the manufacture of semiconductors. On the one hand, the EU wants to localize the production of semiconductors in Europe and is investing 43 billion euros, and on the other hand, the European Parliament wants to ban the materials needed for this. I see a big contradiction there. I think such a decision will have massive consequences for the EU economy and its competitiveness.
		Answer to specific info request 1: For use to deliver cleaning & disinfecting chemicals in : Food and Beverage industry Semiconductor industry Chemical Industry Laundries , Restaurants and Hotels

	Germany	Answer to specific info request 6: If chemicals that can only be used with this plastic are not used, there is a risk that the desired public hygiene effect will not be achieved. This will have a great influence on the spread of diseases that could result from the lack of hygiene in the production of food.
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3915	Date: 2023/04/20 11:11 Content: Scope or restriction option analysis Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Germany Company name confidential: Yes	General Comments: We appreciate the intent to drastically reduce the negative effects of our industry on our nature and environment. In general, we believe it is the right approach to restrict PFAS. This comment is aimed to highlight two critical aspects in this restriction, do make sure it is done the right way. 1) the restriction MUST BE globally valid. IF its not, suppliers will buy PFAS from ASIA or elsewhere and make fortunes with these trades. As a result, our environment is still harmed in equal extents, yet EUROPE is once more boosting the ASIAN or other foreign economies. IF restricting PFAS globally is out of the powers of ECHA, well then it is not the right time yet to deploy that restriction. 2) Please make sure, that the restriction is focusing on the correct group of PFAS, especially considering the molekular composition of the material. As per our research, FKM should not be considered an equally dangerous material compared to other PFAS. In trust that ECHA is making the right choices here. Best regards Dennis Behnisch
		Answer to specific info request 8: See point 1 above.

3916	Date: 2023/04/20 11:42 Content:	General Comments: Fluoropolymers play an important role in numerous technologies and industrial processes: medical applications, defense & aerospace, automotive (including e-vehicles), hydrogen, semiconductor, and energy - including nuclear.
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	Scope or restriction option analysis Hazard or exposure Environmental emissions Baseline Description of analytical methods Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: National Authority Org. name: ██████████ Org. country: Romania Company name confidential: Yes	Considering the socio-economic value, on the other hand, fluoropolymers are polymers of low concern for human health and the environment.
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3917	Date:	General Comments:
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	2023/04/20 13:48 Content: Hazard or exposure Environmental emissions Type: Individual Country: Finland	I would like to highlight one effect of PFAS's that never seems to be mentioned: the hazard to birds. It's been known for decades (the 1970's) that having birds in the same space with PFAS fumes can be fatal. This has been seen in pets (canaries in kitchen area, 'teflon toxicosis') and fowl (e.g., chickens exposed to PTFE-coated heat sources). Further, the substances may be harmful to avian reproduction. I'm listing a few sources below (many more are also available online). Interestingly, even the Teflon brand warns about the toxic effect: https://www.teflon.com/en/consumers/teflon-coatings-cookware-bakeware/safety/bird-safety https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3276392/ https://www.vet.cornell.edu/animal-health-diagnostic-center/news/polytetrafluoroethylene-ptfe-teflon-toxicosis-ducks https://tvmdl.tamu.edu/2021/05/05/polytetrafluoroethylene-toxicosis-teflontm-toxicity/ https://vcahospitals.com/know-your-pet/teflon-polytetrafluoroethylene-poisoning-in-birds https://www.ewg.org/research/canaries-kitchen Avian reproduction: https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=357537&Lab=CCTE Exposure and Effects of PFAS on Birds (figshare.com) https://www.serdp-estcp.org/projects/details/bc88c0f1-9dee-4c17-ac9c-2bb0ee1aa4fc/food-web-exposure-and-consequent-effects-of-pfas-on-birds https://www.diva-portal.org/smash/get/diva2:1137416/FULLTEXT01.pdf
3918	Date:	General Comments:

2023/04/20 16:49 Content: Scope or restriction option analysis Hazard or exposure Environmental emissions Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: <redacted> Org. country: United Kingdom Company name confidential: Yes Attachment:	Dear Sir, Proposed EU REACH Restriction of PFAS - Fluoropolymers As the Owner and Managing Director of Holscot Advanced Polymers Limited, I write to you to register our objection to the proposed EU REACH restriction of certain materials currently classified as PFAS, and to request that the proposal is modified, which I will justify in the following pages, to exclude Perfluoroalkoxy Alkane (PFA), Fluorinated Ethylene Propylene (FEP) and Ethylene Tetrafluoroethylene (ETFE). In line with the published public consultation schedule starting 22nd March 2023 and ending 22nd September 2023, I also register with you our request for a derogation from the restriction for our uses of the following fluoropolymers; PFA, FEP and ETFE, in the event that the modifications are not accepted. Who is Holscot Advanced Polymers and what do we do? Holscot is a UK Private Limited Company with registered offices in UK, Netherlands and Germany. We have manufacturing in England, Scotland and Netherlands. We buy PFA, FEP and ETFE Fluoropolymers and make/convert/manufacture these into a large portfolio of products, sold business to business. The products solve the technical problems of industry and greatly benefit society by using the amazing properties of these fluoropolymers that no other materials possess. Why we are opposed to the restriction ? The restriction is based on the grounds of materials persistence. Whereas the scope of EU REACH is to protect from harm, humans and the environment (article 68 (1) REACH. Persistence is not an indication of harm. Persistence is out of scope of EU REACH remit and as such their restriction of chemicals for the purpose of persistence is not valid. The restriction classifies PFAS as “Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom without any H/Cl/Br/I attached to it.” Whereas the harmful PFAS are a small subset of this classification. The chemical properties and risk associated with one chemical group does not transmit to every instance of that group when present in another polymer. The 1995 US Polymer Exemption Rule was introduced to prevent such blanket restriction which it deemed was unnecessary. Thus the risk associated with a group of concern must be proven in each instance of application in a polymer chemical.
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	<redacted> Privacy statement: This information contains commercially sensitive and proprietary information that cannot be shared.	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/polymer-exemption-new-chemicals The environmental and toxicological profiles are distinctly different in Fluoropolymers solids than the majority of other PFAS liquid chemicals. The assumption that chemical properties are transferred to every instance of occurrence is unfounded and as such the restriction is invalid. Annex 68 of the Proposed Reach Restriction requires that Fluoropolymers which “pose risk to human health or the environment that is not adequately controlled and needs to be addressed”. Fluoropolymers are inert and do not cause harm to humans or the environment. Fluoropolymers are used for medical applications where devices are inserted and remain in the human body. These have been in use for over 60 years which is proof of their lack of harm and toxicity to humans. https://www.nordsonmedical.com/Components-and-Technologies/Medical-Tubing/PTFE-Tubing/#:~:text=PTFE%20has%20been%20used%20in,is%20an%20ideal%20catheter%20liner. The CJEU has held that a risk cannot be purely hypothetical: “[purely hypothetical risks based on mere hypotheses that have not been scientifically confirmed cannot be accepted. To make the maintenance of the authorisation of a substance subject to proof of the lack of any risk, even a purely hypothetical one, would be both unrealistic in so far as such proof is generally impossible to give in scientific terms since 'zero risk' does not exist in practice”. Fluoropolymers do not break down to form harmful chemicals, as has been proven by the Danish EPA. They have been classified as polymers of low concern as documented in the Society of Environmental Toxicology and Chemistry by BJ Henry published 9th February 2018. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035 Fluoropolymers are also “food approved” by the FDA in America, so viewed as very safe to humans. Fluoropolymers are certified not to combust and are proven self extinguishing for example used in the fire proofing of wires. This is an established major use in high rise buildings World wide (“plenum cable”), this application alone uses 1000’s of tons of melt processable Fluoropolymers. Fluoropolymers meet the OECD Polymer of Low Concern (PLC) criteria. They are non-toxic, not bio available, non-water soluble and non-mobile molecules and are deemed as such to have no significant
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		environmental and human health impact. https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm The proposed restriction plans enforcement through the concept of “use”. There are millions of uses of our products, many that we are not privileged to be informed about, owing to non-disclosure by certain customer and national bodies. So, the proposed method of restriction and derogation is unworkable. In summary, the proposed restriction is :- • Legally out of scope of EU REACH • Technically insecure • Seeks to regulate safe polymers • Acts in a manner that is un-enforceable The restriction of Fluoropolymers is illogical, irrational and unreasonable. Because it is outside of the legal scope of EU REACH the restriction will not stand up in a Court of Law and is not supported by scientific data)see Fluoropolymers and the Stockholm POP Criteria. I urge you to reconsider the proposed “blanket ban” on all PFAS chemicals and treat Fluoropolymers as a deserved separate group of chemicals and remove all derogation time limits as per my enclosed supporting “Derogation Request” documents: Jet Aeroplane Engine Protective Sleeves and Breathers FEP, PFA and ETFE covered “O” Rings General extrusions of FEP, PFA and ETFE tubing General extrusion of FEP, PFA and ETFE film FEP Protective Covers used in Lighting Applications Heat Shrink Roller Covers Heat Shrinkable FEP and PFA tubes and film for special applications eg: electric vehicle systems FEP Flange Shields Satellite Fuel Tank Containment in FEP Secondary Containment for industrial purposes including food and beverages Nuclear Waste FEP Secondary Containment Bags Vacuum formed structures in FEP and PFA
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	Industrial Conveyor Belts in FEP Hose Liners in White Pigmented FEP ETFE Architectural Film structures FEP and PFA used for composite parts manufacture Holscot Group are dedicated to the environmentally safe use of melt processable Fluoropolymers. We continue to develop a closed loop/reuse cycle for our materials. Our division “Recycleflon” already recycles over 85% of our own scrap in FEP and PFA Polymers. We will seek ways to extend this facility to our customers “end of life” products and materials. Yours faithfully D N Joyce Managing Director and Owner Holscot Advanced Polymers Alma Park Road Grantham NG31 9SE UK Answer to specific info request 1: Jet Aeroplane Engine Protective Sleeves and Breathers FEP, PFA and ETFE covered “O” Rings General extrusions of FEP, PFA and ETFE tubing General extrusion of FEP, PFA and ETFE film FEP Protective Covers used in Lighting Applications Heat Shrink Roller Covers Heat Shrinkable FEP and PFA tubes and film for special applications eg: electric vehicle systems FEP Flange Shields Satellite Fuel Tank Containment in FEP Secondary Containment for industrial purposes including food and beverages Nuclear Waste FEP Secondary Containment Bags Vacuum formed structures in FEP and PFA Industrial
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		Conveyor Belts in FEP Hose Liners in White Pigmented FEP ETFE Architectural Film structures FEP and PFA used for composite parts manufacture Answer to specific info request 2: "In manufacture" we recover and reuse 11% of our annual tonnage of fluoropolymer use and this figure is increasing year on year. Actual amounts are confidential. Fluoropolymers do not contain the harmful PFAS PFOA, PFOS, PFNA, HFPO-DA, PFHxS, PFBS. PFOA/PFOS. Certification can be supplied on request. (this runs to more than the permitted file size attachment) "In use" there are no emissions in the products produced by Holscot Advanced Polymers Limited, as these products do not degrade and are not water soluble. Therefore 0% emissions. Regarding the "End of Life Phase" phase Holscot Advanced Polymers Limited would be willing to accept end of life products to put through our recycling process. The current uptake from our customers has been low. Answer to specific info request 3: End of Life products can be safely incinerated in Ceramic ovens. Fluoropolymers do not contain the harmful PFAS PFOA, PFOS, PFNA, HFPO-DA, PFHxS, PFBS. PFOA/PFOS. Certification can be supplied on request. (this runs to more than the permitted file size attachment) Answer to specific info request 4: Fluoropolymers do not contain the harmful PFAS PFOA, PFOS, PFNA, HFPO-DA, PFHxS, PFBS. PFOA/PFOS. Certification can be supplied on request. (this runs to more than the permitted file size attachment) Answer to specific info request 5: Tonnage usage: 18% Lighting applications 30% O-rings (transport and industry) 14% Aerospace 24% General extrusions for Industrial applications 13% Other special applications 1% Hose liners Emissions are zero as fluoropolymers do not degrade. Answer to specific info request 6: We have a list of missing uses and submit exemption request for all of these, which are added as attachments. The alternatives have been considered as part of these exemption requests. Jet Aeroplane Engine Protective Sleeves and Breathers FEP, PFA and ETFE covered "O" Rings General extrusions of FEP, PFA and ETFE tubing General extrusion of FEP, PFA and ETFE film FEP Protective Covers used in Lighting Applications Heat Shrink Roller Covers Heat Shrinkable FEP and PFA tubes and film for special applications eg: electric vehicle systems FEP Flange Shields Satellite Fuel Tank Containment in FEP Secondary Containment for industrial purposes including food and beverages
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		Nuclear Waste FEP Secondary Containment Bags Vacuum formed structures in FEP and PFA Industrial Conveyor Belts in FEP Hose Liners in White Pigmented FEP ETFE Architectural Film structures FEP and PFA used for composite parts manufacture
		Answer to specific info request 7: The assessment of these is covered in the documents attached, in summary:- i) Technically and economically feasible alternatives are not available. ii) The alternatives cannot be made ready by the implementation date, nor could they be qualified, certified or approved by the governing industry bodies. iii) alternatives do not exist
		Answer to specific info request 8: There are no viable alternatives, please see the exemption request documents attached.