**General comments and answers to specific information requests**

**Specific information requests:**

1. **Sectors and (sub-)uses**: Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.
2. **Emissions in the end-of-life phase**: The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:
3. Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.
4. If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.
5. **Emissions in the end-of-life phase**: With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.
6. **Impacts on the recycling industry**: To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:
7. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).
8. The measures that recyclers would need to take to achieve the proposed concentration limits.
9. The costs associated with these measures.
10. **Proposed derogations – Tonnage and emissions**: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.
11. **Missing uses – Analysis of alternatives and socio-economic analysis**: Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:
12. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
13. The key functionalities provided by PFAS for the relevant use.
14. The number of companies in the sector estimated to be affected by the restriction.
15. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.
16. For cases in which **alternatives are not yet available**, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.
17. For cases in which **substitution is technically and economically feasible** but more time is required to substitute:
    1. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);
    2. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
    3. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);
    4. information on the benefits for alternative providers.
18. For cases in which **substitution is not technically or economically feasible**, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.
19. **Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis**: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

1. **Other identified uses – Analysis of alternatives and socio-economic analysis**: Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.

For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.

More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

1. **Degradation potential of specific PFAS sub-groups**: A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.
2. **Analytical methods**: Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

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| 3919 | Date:  2023/04/20 17:42  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Austria  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  Why Fluoropolymers in the Chemical Industry for sulfuric acid?  Sulfuric acid (H2SO4) is the most widely used acid worldwide and essential for many industrial sectors (e.g. batteries, fertilizer production, production of other chemicals e.g. HF, semiconductor, metallurgical processes, …). A significant amount of the world wide used H2SO4 is produced using the welt sulphuric acid (WSA) process. To handle the highly concentrated H2SO4 during production as well as the hot flue gases, fluoropolymers are essential for an economic production (reduced maintenance and reduced down-time) and also essential for a safe and environmental friendly production during the whole live-time.  When it comes to the chemicals industry, fluoropolymers allow for the safe production, storage, handling and use of chemicals through protective equipment and linings. Their chemical stability allows them to be resistant to some of the most corrosive substances on the market and as a result protecting works and equipment from harm.  Production, storage, transport an use of chemicals and other hazardous materials can inevitably carry potential risks. Moreover, history has shown that accidents can not only have economic impacts, but also irreparable consequences on human lives and the environment. Mitigating such risks through rigorous safety management whilst simultaneously ensuring efficiency and availability is a major challenge for today’s worldwide chemical industry.  In our view, the Annex XV restriction report does not cover relevant and essential uses of fluoropolymers in the critical sector “chemical industry”: Pipelines, storage tanks and transportation containers for the handling of chemicals because they are mechanically solid, chemically resistant and stable even in harsh and corrosive environments. |
| Answer to specific info request 1:  The specific Sector “PFA Fluorpolymers used in the WSA (Wet Sulphuric Acid) Sulphuric acid production” process is not listed in Annex XV. |
| Answer to specific info request 2:  Today most PFA raw materials are produced using fluorinated polymerization aids that may remain in extremely small amounts (ppm) within the PFA and have the potential to leach-out during the use phase. To reduce the risk of small molecular PFAS to be emitted from fluoropolymers, it is desirable to produce them without fluorinated polymerization aids. Production: During the extrusion of sheets, pipes and welding rods, the PFA is heated up to about 370 °C and kept at this temperature for about 10 Minutes, before it is cooled down again. According to Drobny et al, we can calculate the emissions of PFA at the extrusion temperature of 370 °C as follows:  33500 kg \* 0.004 %/h /100 \*10/60 = 0,22 kg Extruding products from about 33500 kg of PFA, is expected to lead to about 0.22 kg of low molecular emissions according to Drobny at al. One should not forget these emission are mainly composed of HF, thus only a fraction of the 0.22 kg/year have the potential to be PFAS. In our facility critical production areas like extruder, extrusion die and calender-rolls are covered with a ventilation hood to suck off possible low molecular substances and HF. The processing gases are afterwards cleaned via a gas scrubber before released into the atmosphere. Measurement show, that low molecular PFAS accumulate in water used in the gas scrubber, thus it is proven that they are removed from the off gases collected above the extrusion line. Usephase During the use phase the PFA is used at a maximum temperature of 260 °C (sometimes it is lower and only temporarily 260 °C is reached). Assuming the worst case of 260 °C, the following emissions can be expected from PFA according to Drobny at all during the lifetime of 15 years:  33500 kg \* 100\*10^-11 %/h /100% \* 24 \* 365 \* 15 = 0.044 kg Considering that this is the worst-case scenario at the topmost application temperature and that not all of the 0.044 kg are PFAS, but mainly HF, the release of PFAS into the environment is negligible during the whole use phase. Additionally, it is expected that the emission are not constant, but are slowly decreasing during the life-time. That the emissions caused by PFA are negligible becomes very obvious when looking at the data presented by ECHA during the webinar on April 5th 2023: Emissions from fluorinated gases, emissions from textiles or emissions from medical devices are expected to be in excess of >>1000 t each year. Thus, restriction need to focus on applications that cause most of the emissions. End of Life: Equipment which is decommissioned after service life (~ 10-15 years depending on the application) will be deopsited under strict governmental rules (hazardous waste) in dedicated landfills or will be incinerated. PFA Products are stable and will not degrade to small molecular PFAS. |
| Answer to specific info request 6:  a) • Due to the increasing environmental regulations the demand of WSA production units is constantly growing. The WSA process efficiently removes sulfur from flue gases to meet todays emission regulations in sulfuric acid production as well as waste incineration plants and power plants. b) The publication Fluoroplastics as Corrosion Protection in Flue Gas Desulphurization Units (VGB Power Techn 4/2007, paper attached below) explains why PFA is successfully used in this specific applications: • Long term chemical resistance of PFA against condensating sulfuric acid (>96 %) at operation temperatures of about 260 °C as well as other acids and chemicals present in the flue gas • Test report Exposure Testing Swerea Kimab (attached to submission) • Official Letter “Freudenberg” Lifetime >10 years (attached to submission) • A long-term leak proof lining system can be achieved under these critical operation conditions • The PFA lining offers simple repair options since the sheet can be welded again after proper preparation in the case of mechanical damages. • Increasing the efficiency of the WSA plant due to an increase in reliability and increased availability (reduced maintenance)  Customer Project report attached => Information about annual tonnage is provided in the attached, confidential document c) In principle, all chemical companies which are using this type of equipment and that are involved in the production and use of sulfuric acid. Additionally, those who build and plan the facilities + producer of the components (like PFA semi-finished products). Affected industrial applications in general: Refinery and petrochemical industry, Metallurgy industry, Coal based industry, Power industry, Viscose industry, Sulfuric acid industry, Production of fertilizers, Semiconductor industry and all users of sulfuric acid d) In the past a multilayer construction was used consisting of the following materials: • Chemical stone lining (direct media contact) • Foam glass layer • Non-welded PTFE sheets (secondary layer) • Chemical protection layer (coating) • Steel tank as a mechanical structure Experience has shown that this multilayer construction is not creating a long-term and leak proof lining system. As a result corrosion of the carbon steel tank by the condensing sulfuric acid happens after a few years (e.g. 3 years). As a result, frequent maintenance and repairs are required. Eventually, it is necessary to remove the lining system, which is already soaked with acid, at great safety expense and to refurbish the steel structure and lining in a further step. As no long-term leak proof lining system can be generated with this multilayer structure, plant safety is reduced significantly. Additionally, the plant availability and reliability is reduced significant due to frequent maintenance intervals  See OMV Project report attached. All materials of this alternative can be purchased in Europe, except the PTFE foil, which could be banned by the PFAS restriction process as well. High-alloy steels like Hastelloy, Inconel and also Titanium, Zirconium are not chemical resistant against the stated operation conditions (Condensing, Fuming Sulfuric Acid at operation temperature of 260 °C); Source/Reference used: Compass Corrosion Guide II Furthermore it is referred to publication in the Sulphur Magazine (number 358, May-June 2015) that explains the chemical resistance of fluoropolymers against sulfuric acid and evaluates possible alternatives. g) Banning PFA would not only cause harm to our business and the business of our suppliers, but to all companies and end users in the chemical industry. Considering that alone the market of sulfuric acid is worth about 13 billion € per year, the effect of banning PFA could have a substantial impact on the whole value chain. Without the WSA production technology the environmental requirements of the SOx exposure can not be fulfilled. In addition, the availability of sulphuric acid in Europe is reduced. Sulfuric acid is used most used acid world wide, used in various applications like (Fertilizer Industry, Chemical industry, Semiconductor industry, metallurgical industry) Negative impact on EU Strategies, Sustainable Development Goals: Semiconductor industry, E-Mobility |

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| 3920 | Date:  2023/04/20 17:52  Content:  Scope or restriction option analysis  Baseline  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Scope or restriction option analysis: The definition of the PFAS family is too broad, as it also includes substances that do not have hazardous properties or pose unacceptable risks, such as fluoropolymers. The inclusion of fluoropolymers in the restriction proposal violates the principle of proportionality. Restricting the use of fluoropolymers will have a huge negative impact on society in the EU. Due to the excellent heat and chemical resistance of fluoropolymers without components of PFAS, the existence of many important industries in Germany and the EU would no longer exist.  Baseline: PTFE, PVDF, PFA approximately 42 tons per year subcontractor for mechanical and plant engineering, mainly chemical industry Chemical pumps for the semiconductor industry and battery separators Chemical pumps for pumping media for the pharmaceutical industry Shut-off devices in highly corrosive plants (flue gas desulfurization) Sealing elements  Other socio economic analysis (SEA) issues: Loss of 15-50 jobs Drop in sales of up to 10% Dismantling of machines and plants and associated costs. Loss/collapse of the entire European business location. Relocation of production to Asia or other countries that do not address the issue. Due to the excellent heat and chemical resistance of fluoropolymers without PFAS components, the existence of many important industrial sectors in Germany and the EU would no longer exist.  Transitional period: From our experience, we can say that for possible substitution, transition periods of several years are necessary to establish alternative products ready for series production. Due to the complexity of the supply chains involving fluoropolymers, a restriction process based on exemptions will not be implemented by the relevant industrial stakeholders.  Request for exemption: Fluoropolymers form a special group of substances within the PFASs, since their properties are completely different. These substances are considered as polymers of low concern, and their use therefore poses no risk to human health or the human health and the environment. For this reason, a comprehensive exemption for this group of substances should be considered under the PFAS restriction proposal. |
| Answer to specific info request 6:  a) 10t PVDF, 30t PTFE, 2t PFA b) outstanding heat- and chemical resistance c) 30 companies in direct relation to our company d) Products are very high price. If cheaper alternatives had the same effect, the cheaper alternatives would certainly be used. In the case of a ban on fluoropolymers for industrial applications, the entire European machinery and plant engineering industry would collapse. Complete sectors of the economy would relocate production to non-European countries. Exceptions are not known. e) Alternatives are not know yet and not possible today. We are supplier for the chemical industry where R&D-procedures require approval times of several years. In addition to a possible transformation phase, further regulatory and/or product-specific approvals and certification steps must be carried out. The ban of PFAS must be considered independently of fluoropolymers such as PTFE/PVDF/PFA, where manufacturers have already addressed this in recent months and years and can produce the fluoropolymers PFAS-free. f) no substitution is known g) Loss of 15-50 jobs just at our company Drop in sales of up to 10% Dismantling of machines and plants and associated costs. Loss/collapse of the entire European business location. Relocation of production to Asia or other countries that do not address the issue. |

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| 3921 | Date:  2023/04/20 21:05  Content:  Information on benefits  Type:  Individual  Country:  Sweden | General Comments:  I support the proposal. It is necessary. |
| Answer to specific info request 1:  Use of PTFE in plastic in most electrical products is wide and often not necessary. It can be substituted. Of course we need to compromise that products may get bigger, cost more or not have all features as of today. The way we design and produce most products is not sustainable and does not cover the real costs. |
| Answer to specific info request 6:  PFAS is used in many applications in electronics. There are alternatives if required to change. |

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| 3922 | Date:  2023/04/20 21:21  Content:  Scope or restriction option analysis  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Zound Industries  Org. country:  Sweden | General Comments:  We support the restriction. A total ban is necessary to change the industry to substitute pfas and find alternatives. |
| Answer to specific info request 1:  PFAS is used in 100s of applications in electronics, as most hard plastics, rubber, sealants, tapes and oil. Also, a lot of PFAS is used to meet too high flammability requirements. It is also necessary to modify safety standards on flammability requirements. |
| Answer to specific info request 4:  It is very hard to get information on pfas for manufacturers so recyclers can not only trust this. Therefore a total ban is required. |
| Answer to specific info request 6:  There are alternatives for many uses in consumer electronics. We are willing to make compromises because the way products are designed and produced today is not sustainable. |

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| 3923 | Date:  2023/04/21 10:34  Content:  Scope or restriction option analysis  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  BAUM Lined Piping GmbH  Org. country:  Germany  Attachment:    <redacted> | General Comments:  There is a broad consensus in this organisation that a large number of PFAS should be banned or limited. The environment is over-polluted - and none of us wants to fall ill. In this respect, we fully support the initiative. However, there is not only one type of "PFAS”. There are some that are dangerous and toxic. They are what it is all about. However, there are also long-chain compounds that are very persistent and do not dissolve, and therefore do not represent an immediate risk to the environment. These compounds are non-toxic, non-mobile and therefore do not accumulate. However, particular attention needs to be paid to the production and, of course, to the end-of-life management of these substances and to a safe disposal or to a recycling system that does not release PFAS compounds into the environment. These are a small number of fluoropolymers, which, in our opinion, represent a clear exception: PTFE, PFA, ETFE and FEP. These substances will be discussed in more detail below (document #0.03). These fluoropolymers are used extensively in industrial plants in the chemical/agricultural and pharmaceutical industries. This is not about the "end products" that are produced in these plants, but rather about the so-called "pre-production". The chemical reaction stages at the very beginning of the production line. To the "average person" these applications remain hidden, as they are not seen in the context of end products. It is, however, the basis of all production processes in which, for example, substances have to be dissolved or cracked to obtain intermediate products from which the final products can be made. In this respect, the 'Chemical/Pharmaceutical' sector under discussion is very similar to the 'Petroleum and Mining' sector, although much larger and more important to the European economy. One example is the use of sulphuric acid, which is also used in mining to extract metals from rocks. Other examples are hydrochloric acid or nitric acid. Even though highly aggressive, these processes have become indispensable in industrial production. However, your draft lacks a detailed consideration of the chemical/crop science and pharmaceutical industries, as you yourself document in your report Annex A, Table A1. However, the value of these industries to the European economy is immense, as shown in the attached document #0.01. For reasons of fairness, we therefore advocate a more intensive analysis of the areas of "industrial applications in chemical/crop science and pharmaceuticals", which have received little attention to date. It is therefore a question of combination: - Additional area: "industrial plants in chemicals, CropScience and pharmaceuticals" - Related to: Fluoropolymers, in particular PTFE, PFA, ETFE and FEP and their applications. The following two papers are intended to provide evidence and documentation of the safety of fluoropolymers, while at the same time demonstrating the enormous importance of the chemical and pharmaceutical industries, which should be given additional consideration in the draft. Part 1: deals with the ECHA draft dated 22.3.23 in relation to "Chemical/CropScience and Pharma", document #0.02 Part 2: deals with fluoropolymers, in particular PTFE, PFA, ETFE, FEP; document #0.03 We are therefore concerned with fluoropolymers (in particular PTFE, PFA, ETFE, FEP), which are on the one hand "polymers of low concern" (non-toxic, non-mobile, non-soluble and non-accumulative), represent closed material cycles, have no serious alternative in the usual high-temperature industrial applications and, if banned, will have serious socio-economic consequences; On the other hand, to be prohibited as there are concerns due to persistence. However: Where "persistent" materials are technically required, and these are precisely those chemical applications, they can only be reasonably replaced by other persistent materials (if replacement is possible at all). It would seem to make more sense to work towards the proper disposal or recycling/reuse of fluoropolymers, as recycling and recirculation processes already exist (successfully), but may not yet be widespread. Hence our proposal:  1. Fluoropolymers, in particular the four fluoropolymers PTFE, PFA, ETFE, FEP identified by the IEAM, should be completely excluded from the ban procedure. 2. The industrial sector / industrial applications in the Chemical/CropScience and Pharmaceutical sector should be examined just as accurately as the other 14 classified sectors, in accordance with its value in the European economy, a derogation should also be established here.  BAUM lined piping GmbH  See documents Non-confidential #0.01, Confidential #0.02 Confidential #0.03 |
| Answer to specific info request 1:  SECTOR: Chemical industry In fact, our comments refer to a sector, which is „not researched in detail“. This sector is „chemical industry“ according to Annex a, Table A1. We would vote to call this sector „Chemical, CropScience and pharmaceutical industry“. SUB-USE: Fluorpolymers In this sector, Fluorpolymer lined pipes, fittings, columns and vessels are widely used as they are persistant against the used agrressive medias in those industry production. Persistance is here the key function. Especially PTFE/PFA/ETFE/FEP are fluoropolymers of low concern, as they are non toxic, insoluble in water, does not accumulate, not hazardous to men and environment (see document #1.01, non-confidential attachments). Please see hereto also: document confidential #2.14 Conversio study |
| Answer to specific info request 2:  Please have a look at the Conversio study attached in „confidential attachments“ document #2.14 |
| Answer to specific info request 3:  Regarding End-of-Life emissions, we can only talk about Fluorpolymers. Incineration here is safe ( see non-confidential document #2.19), since HF-gas as product of emission can be recovered in a recycling pathway and can be re-used in new production of PTFE. Please see also document # 2.17a „Recycling of PTFE“ in combination of the EU report „JRC Science for Policy report – Best available Techniques Reference document for waste incineration“. WE have to admit, that this closed material cycle is not yet implemented worldwide, so it would need some regulation on that. Additionally, beside incineration, we would like to draw your attention on other – already existend ! – closed material-cycle pathways for Fluorpolymers, such as PFA and PTFE: PFA Recycling: BAUM is doing that successfully – all PFA production waste will be re-granulated by third party and this material is re-used in actual production. Please see non-confidential document #2.08 PTFE Recycling: Since 2014, there is a recycling plant existing (chemical park Gendorf, Germany), which recycles at an efficiency of 90% EOL PTFE into Monomeres, which will be re-used in new production. Please see non-confidential documents # 2.06 Gendorf and #2.07 InVerTec |
| Answer to specific info request 5:  As you can find under „general information“ comments from our side, we believe, chemical industry (or more precise: Chemical/CropScience/Pharma Industry) should be implemented in the derogations (the most similar field is listed at 6f „fluoropolymer applications in petroleum and mining industry“. As an answer to your question 5 we propose the implementation of: 6 g.) fluoropolymer applications in chemical/CropScince/pharma industry BAUM amount of fluoropolymers in production per anno: 300 to x 86% = 255 to The remaining material (14%) goes to: 6 f.) fluoropolymer applications in petroleum and mining industry BAUM amount of fluoropolymers in production per anno: 300 to x 9% = 27 to xx.) fluorpolymere applications in energy / hydrogen production BAUM amount of fluoropolymers in production per anno: 300 to x 5% = 15 to |
| Answer to specific info request 6:  Missing uses: chemical industry – more precise: Chemical/CropScience/Pharma Industry Please refer to confidential document #2.14 Conversio study a. In 2020 / EU: chemical/pharma industry 14,4 kto fluoropolymers in use/ 11,5 kto collected waste (which is 80%) b. Key functionalities of fluoropolymers in those industries is the persistance against almost all organic acids. Fluoropolymers are in use as lining for pipelines, vessels, columns and reactors for all chemical processes in that industry. As the work with high aggressive media is hazadorous and dangerous, fluoropolymers protect men,equipment and environment from damages. With their wide range of functionalities (chemical resistance, working temp from -60°C up to 230°C, persistant over decades) there are no real alternatives covering the whole range of functionalities. c. We can only answer for BAUM GmbH: we have more than 2500 customers who will be effected by such a restriction. Please see confidential document #2.01 „BAUM Kundenliste“ d. For alternatives, please refer to confidential document #0.03 point 3 and confidential document #2.15 e. We do not see a realistic upcoming alternative to fluoropolymers, as the key function „persistance“ can only be replaced by other „persistant“ product. f. ----- g. For socio-economic impacts in case of a restriction, please check: i. Confidential attachment document #0.03 point 4 ii. Confidential attachment document #2.14 Conversio study iii. Confidential attachment document #2.15 Chemservice study iv. Non- Confidential attachment document #2.16 Final SEA |
| Answer to specific info request 7:  As you can find under „general information“ comments from our side, we believe, chemical industry (or more precise: Chemical/CropScience/Pharma Industry) should be implemented in the derogations (the most similar field is listed at 6f „fluoropolymer applications in petroleum and mining industry“). So we propose the implementation of: 6 g.) fluoropolymer applications in chemical/CropScince/pharma industry Given this, we can say to your question 7 i.) PEEK could be an alternative regarding persistance and temperature ii.) PEEK is existing already iii.) Problem: PEEK is not available in required amounts to replace fluoropolymers, and extremely expensive (120 €/kg depending on requested amount, whereas PTFE costs 15-25 €/kg), see confidential document #2.20. On top, production of PEEK is very energy-intensive. However: This material is not yet being authorized for such applications. It needs further developments and long-run testings already from producer side. Further on, this material has to be tested on site under real conditions (this will take years). Additionally, Downstream-users have to implement that material into their own specifications, after successful testing, this is probably the hardest hurdle, as home-grown specifications were originated over decades of experience…….so estimated timeline is something between 10-20 years. Please see non-confidential document #2.02 PEEK confidential document #2.20 PEEK pricing |
| Answer to specific info request 8:  Already answered in question 6 and given attachement documents there Missing uses: chemical industry – more precise: Chemical/CropScience/Pharma Industry Please refer to confidential document #2.14 Conversio study a. In 2020 / EU: chemical/pharma industry 14,4 kto fluoropolymers in use/ 11,5 kto collected waste (which is 80%) b. Key functionalities of fluoropolymers in those industries is the persistance against almost all organic acids. Fluoropolymers are in use as lining for pipelines, vessels, columns and reactors for all chemical processes in that industry. As the work with high aggressive media is hazadorous and dangerous, fluoropolymers protect men,equipment and environment from damages. With their wide range of functionalities (chemical resistance, working temp from -60°C up to 230°C, persistant over decades) there are no real alternatives covering the whole range of functionalities. c. We can only answer for BAUM GmbH: we have more than 2500 customers who will be effected by such a restriction. Please see confidential document #2.01 „BAUM Kundenliste“ d. For alternatives, please refer to confidential document #0.03 point 3 and confidential document #2.15 e. We do not see a realistic upcoming alternative to fluoropolymers, as the key function „persistance“ can only be replaced by other „persistant“ product. f. ----- g. For socio-economic impacts in case of a restriction, please check: i. Confidential attachment document #0.03 point 4 ii. Confidential attachment document #2.14 Conversio study iii. Confidential attachment document #2.15 Chemservice study iv. Non- Confidential attachment document #2.16 Final SEA |

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| 3924 | Date:  2023/04/21 13:54  Content:  Request for exemption  Type:  Individual  Country:  Germany  Attachment: | General Comments:  Please see attached Letter and supplementary documents. |
| Answer to specific info request 9:  Please see attached Letter and supplementary documents. |

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| 3925 | Date:  2023/04/21 14:42  Content:  Environmental emissions  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  RECHARGE  Org. country:  Belgium  Attachment: | Answer to specific info request 1:  High performance, advanced rechargeable and lithium batteries: • Lithium-ion rechargeable batteries (also known as Li-ion batteries) • Lithium (Li) primary batteries (also known as primary Lithium batteries) • Nickel–based rechargeable batteries (Ni-Cd and Ni-MH) • Metal air batteries • Zinc oxide batteries • Silver oxide batteries • Sodium-ion (Na-ion) rechargeable batteries • Zinc-ion (Zn-ion) rechargeable batteries • Solid-state batteries • Lithium metal rechargeable batteries • Other battery technologies currently under research |
| Answer to specific info request 2:  See attached document |
| Answer to specific info request 3:  See attached document |
| Answer to specific info request 4:  See attached document |
| Answer to specific info request 5:  See attached document |
| Answer to specific info request 6:  See attached document |
| Answer to specific info request 8:  See attached document |

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| 3926 | Date:  2023/04/21 17:07  Content:  Scope or restriction option analysis  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  <redacted>  Org. country:  Norway  Company name confidential:  Yes  Attachment: | General Comments:  To include the fluoropolymers within the scope of all PFAS does not respect the principle of proportionality. Fluoropolymers are OECD polymers of low concern; they are widely used in many applications and markets. For the manufacturing of fluoropolymers nowadays NON-fluorinated process aids are also available. Fluoropolymers are mostly used when no other materials are technical possible due to the unique material properties, see for example analyses for the automotive industry in the attachment. A limitation will cause in the automotive industry a huge negative impact, due increased safety risk for vehicles, not meeting emission legislations of NOx, particles and HC and hindering downsizing of drivelines / engines, thus not meeting CO2 legislations/ fuel reductions. Also from a waste, recycling point and avoiding they remain in the environment the content of the fluoropolymers on a vehicle is very very low compared to other plastics on the vehicle. Thus very limited effect if they will be banned, whereas developing alternatives in the automotive industry ( more than 7-10 years) will have a larger negative effect. |
| Answer to specific info request 1:  Transport sector (and off road vehicles and stationary engines ) |
| Answer to specific info request 7:  see attachment. Fluoropolymers like PTFE and ETFE are often used for hoses and tubes to transfer fluids (water, oil, biofuel) or gases (air, exhaust) on On-road and Off-road engines and vehicles. Normally for safety- and emission critical applications and harsh conditions. As cost is a key driver in the automotive industry and Fluoropolymers are relative expensive, they only will be designed in when no other alternatives are present. To develop and also to validate alternatives, it will mean to use different technologies for the function/ system and this will take by the OEM's a long time , ie more then 7 - 10 years. No short /midterm drop- ins are available due to the increasing tighter legislations for fuel and emission reductions, which driving downsizing of engines, more emission reduction systems and hybrids. This all leads to increasing operating temperatures, flexible hoses and tubes due to tighter routing cq space constraints on engine and vehicles and the requirement to reduce weight of vehicle and component driving the need for fluoropolymers like PTFE and ETFE. |

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| 3927 | Date:  2023/04/24 04:56  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Japan  Company name confidential:  Yes | Answer to specific info request 1:  gasket packing |

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| 3928 | Date:  2023/04/24 08:32  Content:  Other socio economic analysis (SEA) issues  Request for exemption  Type:  Individual  Country:  Germany | General Comments:  We are manufacturing high precision parts for the aviation industry. Since we use aerospace material PTFE+bronze, we ask for further examination if the mentioned material is really that harmful as stated in the proposal of the ECHA. Further defferentiation should be carried out. |
| Answer to specific info request 1:  While machining aerospace material PTFE+bronze, machines are secured and vacuumed. Therefore, every output is filtered before releasing it to the environment. |
| Answer to specific info request 5:  We are machining round about 0,5 tonnes during 3 years of aerospace material PTFE+bronze bar material |
| Answer to specific info request 8:  Regarding the raw material marked cost increase were significantly during the recent year. A restriction regarding raw material will have a further (negative) impact on the development of costs. This will also automatically have an impact on productivity and thus profitability. |

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| 3929 | Date:  2023/04/24 11:12  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  CDR Pompe S.r.l.  Org. country:  Italy  Attachment: | General Comments:  1. Scope or restriction option analysis: Including fluoropolymers in the restriction proposal does not meet the goal of protecting human health and the environment. Fluoropolymers are used in many applications where dangerous, hazardous, corrosive or pure fluids are handled and where metallic or “traditional” plastic materials fail to meet the requested duties, in terms of corrosion resistance, liquid adsorption or contamination of pure substance. For example, most fluoropolymers such as PVDF, are capable to pump concentrated sulfuric acid where most of metal made components fail to met the requested chemical compatibility, causing increased risk of: 1. Leakage of hazardous media to the environment, with higher risk of pollution; 2. To the personnel involved in operating pumping equipment; 3. Increased plant operating costs, due to higher level of maintenance requested. Also, for pumping acetic acid, fluoropolymers are the best choice, for example PVDF offer the best chemical compatibility where all metallic pumps have chemical compatibility problems, leading again to increased risks of premature leakage of hazardous media, increased risk to operating personnel and increased maintenance costs due to less chemical resistance of metal made pumps. Other examples of pumped media that require fluoropolymers lining on pump components and cannot be pumped with metal alloys, without increased risks are: acetil-salicilic acid, benzoic acid, butyric acid, calcium acid sulfate, carbolic acid, carbonic acid, chloric acid, chloroacetic acid, chlorinated fluids, chromic acid in concentration from 1% to above 50%, formic acid etc. For reference on materials chemical compatibility see: https://www.graco.com/content/dam/graco/ipd/literature/misc/chemical-compatibility-guide/Graco\_ChemCompGuideEN-B.pdf  Banning all fluoropolymers means also producing or using less safe, reliable and durable fluid handling equipment in chemical processes, pharmaceutical processes and in oil and gas industry, more prone to risk of leakages that can expose workers that operating on site to a major risk of serious injuries or short/long term health diseases, derived by came in contact with hazardous/dangerous media. Leakage coming from fluid handling equipment (pumps) can have adverse effects also on the environment, when moving hazardous, corrosive or dangerous fluids. Banning all fluoropolymers and having thus less reliable equipment, lead to a major risk of fluid handling equipment (pumps and gaskets) leakage, worsening the environmental footprint of chemical, pharmaceutical and oil & gas process plants. Instead of banning fluoropolymers we see it as more reasonable to regulate waste management of components in which fluoropolymers are present, in order to minimize environmental impact.  2. Hazard or exposure No data  3. Environmental emissions No data  4. Baseline Actual use of fluoropolymers, based on our data, is about 2600 kg/year divided mainly between PFA, ETFE, PVDF.  Products delivered: a. Lined centrifugal pumps for corrosive/hazardous fluids. b. Mechanical seals for corrosive hazardous fluid containment.  Sectors of use: a. Chemical process plants. b. Pharmaceutical process plants. c. Oil & gas.  5. Description of analytical methods No data  6. Information on alternatives Considering our main applications, for pumping acids like: hydrochloric acid, hydrofluoric acid, acetyl salicylic acid, chloric acid or chemicals like: bromine, fluorinated fluids, chromium and barium sulfate, chlorine and chlorinated water, fluoropolymers are the most consistent/unique choice of material lining because of their excellent chemical compatibility with these pumping media (liquids), low permeation rate and low degradation with respect to metallic materials. Considering non fluorinated polymeric material, they offer less chemical compatibility and narrower working temperature range compared to fluoropolymers. Considering production costs, both metallic materials and fluorine free polymers have higher production costs compared to fluoropolymers. For nickel-based alloy, for example, raw material costs are 3 to 5 times higher than PFA. If one keep in mind that, for lined pump components, the use of fluoropolymer is limited to maximum 3 kg when a component fully made of metal weigh 40 to 50 kg the price difference between the two components become more than evident. Given all the considerations above we see no alternative material that can substitute fluoropolymers in chemical process, pharmaceutical process and oil & gas sectors, both from technical and costing points of view. For more information on chemical compatibility of pumped media see reference: https://www.graco.com/content/dam/graco/ipd/literature/misc/chemical-compatibility-guide/Graco\_ChemCompGuideEN-B.pdf  7. Information on Benefits Use of fluoropolymers as lining materials for pumps and fluid handling devices or gaskets allows to transport and store hazardous fluids like … with minimum risk for human health and environment, guarantees safe equipment operation and less maintenance and operating costs. From corrosion resistance point of view, components lined with fluoropolymers guarantee the highest level of durability compared to any metal made component, in pumping corrosive media. Fluoropolymers are also totally inert materials, that means: a pump lined with a fluoropolymer like PFA, PVDF or ETFE does not contaminate the pumped liquid, its purity remains unchanged. In addition to all the characteristics above, fluoropolymers can also withstand high temperature liquids, make lined pumps suitable to work in hot and harsh environments without containment fails, losses or leakages. Being more chemically inert and less prone to corrosion, fluoropolymers allow pump manufacturers to design and build lighter components with benefits to environmental impact (reference: https://vantonpump.com/tl-167-plastics-or-metal-which-material-is-right-for-your-pump/). Considering manufacturing effort, lined components (ETFE) emission is about 10 kg of CO2 for each EFTE kg, while nickel alloy components emissions are about 13 kg of CO2 emitted for each nickel alloy kg. Since lined components necessitate less material than nickel alloy components to be produced (a pump casing lined with fluoropolymer contains maximum 3 kg of EFTE, PFA or PVDF, when a metal made pump casing contains 40 to 50 kg of metal) the environmental footprint of fluoropolymers is a lot lighter than its metallic alternatives. (references: https://nickelinstitute.org/ , https://www.cableizer.com/documentation/EEC/).   8. Other socio-economic analysis No data  9. Transitional period Considering that today there isn’t any real alternative to fluoropolymers for hazardous and corrosive fluid handling applications and no recent developed new material has proven to have better characteristics of fluoropolymers in this fields, we think it is premature to fix time limits to the use of these materials. At the time of writing seems more reasonable to exempt all fluoropolymers from being banned. When there will be real and effective alternatives to these materials, in terms of corrosion resistance, hazardous substances containment and chemical inertness it will be possible to discuss again about fluoropolymers regulation.  10. Request for Exemption Since studies on fluoropolymers don’t highlight certain evidence of hazards for human health and are considered, unlike PFAS, of low concern, a broad exemption for this group of substances should be considered within the PFAS restriction proposal. |
| Answer to specific info request 1:  Oil & gas and mining, lined pumps and auxiliary equipment. |
| Answer to specific info request 6:  Sector: Chemical and Pharmaceutical process sector. Components involved: Lined pumps and auxiliary equipment. As specified in Annex XV restriction report for oil & gas and mining sector, also for chemical and pharmaceutical process plants, the only alternative to fluoropolymers for pumping hazardous or corrosive liquids are metallic materials, in particular special alloys like bronze or nickel alloys. As stated also in Annex E, paragraph 2.15 metallic materials used to substitute fluoropolymers are less flexible, produce heavier components and are more carbon intensive. Corrosion resistance and chemical inertness of metals are poorer compared to fluoropolymer materials, making them less suitable compared to fluoropolymers from a safety point of view, when handling corrosive, hazardous media or substances that must be kept at a high level of purity. Moreover, metallic pumps and fluid handling devices need gaskets capable of containing liquids pumped or handled. These gaskets need the same corrosion resistance and chemical inertness characteristics of the other parts of the pump, with the necessary elasticity to fill all the gaps between pump components, in order to prevent any fluid leakage from pump. Metals gaskets don’t meet all the requirement above, making them unsuitable to effectively contain corrosive or hazardous media. Composite gaskets are also unsuitable because often resins used to bond fibers can be attacked by corrosive media. Rubber based alternatives suffer at temperatures above 120 – 150 °C and chemical compatibility is not as broad as for fluoropolymers. Considering pump lined components, the alternative material proposed in the Annex E, paragraph 2.15, aren’t suitable for temperatures higher than 150 °C and chemical compatibility is not as broad as for fluoropolymers. Given the motivation above, it is clear that: any of the alternative material specified for example in Annex E 2.15, that should be used to substitute fluoropolymers as materials for lined components or gaskets, present an increased risk of leakage, premature failure or degradation of pump/gaskets components, causing hazardous, toxic or corrosive media release to the environment, with high risk also for personnel working with this machinery. Since at the time of writing there are no valid alternatives to fluoropolymers and it is not foreseen any big development in the very next years, the request is an exemption for fluoropolymers used in chemical processing plants equipment and pharmaceutical processing plant equipment. Banning fluoropolymers in chemical and pharmaceutical process industry will impair European capacity to produce intermediate products necessary constituents of all drugs actually on the market, moreover the dismantling of drugs, fertilizers and other chemical process plants, would lead to unemployment of more than 400 000 operators, considering also the supply chain and depriving Europe of a strategic sector. |
| Answer to specific info request 7:  Sector: Chemical and Pharmaceutical process sector. Components involved: Lined pumps and auxiliary equipment. As specified in Annex XV restriction report for oil & gas and mining sector, also for chemical and pharmaceutical process plants, the only alternative to fluoropolymers for pumping hazardous or corrosive liquids are metallic materials, in particular special alloys like bronze or nickel alloys. As stated also in Annex E, paragraph 2.15 metallic materials used to substitute fluoropolymers are less flexible, produce heavier components and are more carbon intensive. Corrosion resistance and chemical inertness of metals are poorer compared to fluoropolymer materials, making them less suitable compared to fluoropolymers from a safety point of view, when handling corrosive, hazardous media or substances that must be kept at a high level of purity. Moreover, metallic pumps and fluid handling devices need gaskets capable of containing liquids pumped or handled. These gaskets need the same corrosion resistance and chemical inertness characteristics of the other parts of the pump, with the necessary elasticity to fill all the gaps between pump components, in order to prevent any fluid leakage from pump. Metals gaskets don’t meet all the requirement above, making them unsuitable to effectively contain corrosive or hazardous media. Composite gaskets are also unsuitable because often resins used to bond fibers can be attacked by corrosive media. Rubber based alternatives suffer at temperatures above 120 – 150 °C and chemical compatibility is not as broad as for fluoropolymers. Considering pump lined components, the alternative material proposed in the Annex E, paragraph 2.15, aren’t suitable for temperatures higher than 150 °C and chemical compatibility is not as broad as for fluoropolymers. Given the motivation above, it is clear that: any of the alternative material specified for example in Annex E 2.15, that should be used to substitute fluoropolymers as materials for lined components or gaskets, present an increased risk of leakage, premature failure or degradation of pump/gaskets components, causing hazardous, toxic or corrosive media release to the environment, with high risk also for personnel working with this machinery. Since at the time of writing there are no valid alternatives to fluoropolymers and it is not foreseen any big development in the very next years, the request is an exemption for fluoropolymers used in chemical processing plants equipment and pharmaceutical processing plant equipment. Banning fluoropolymers in chemical and pharmaceutical process industry will impair European capacity to produce intermediate products necessary constituents of all drugs actually on the market, moreover the dismantling of drugs, fertilizers and other chemical process plants, would lead to unemployment of more than 400 000 operators, considering also the supply chain and depriving Europe of a strategic sector. |
| Answer to specific info request 8:  Sector: Chemical and Pharmaceutical process sector. Components involved: Lined pumps and auxiliary equipment. As specified in Annex XV restriction report for oil & gas and mining sector, also for chemical and pharmaceutical process plants, the only alternative to fluoropolymers for pumping hazardous or corrosive liquids are metallic materials, in particular special alloys like bronze or nickel alloys. As stated also in Annex E, paragraph 2.15 metallic materials used to substitute fluoropolymers are less flexible, produce heavier components and are more carbon intensive. Corrosion resistance and chemical inertness of metals are poorer compared to fluoropolymer materials, making them less suitable compared to fluoropolymers from a safety point of view, when handling corrosive, hazardous media or substances that must be kept at a high level of purity. Moreover, metallic pumps and fluid handling devices need gaskets capable of containing liquids pumped or handled. These gaskets need the same corrosion resistance and chemical inertness characteristics of the other parts of the pump, with the necessary elasticity to fill all the gaps between pump components, in order to prevent any fluid leakage from pump. Metals gaskets don’t meet all the requirement above, making them unsuitable to effectively contain corrosive or hazardous media. Composite gaskets are also unsuitable because often resins used to bond fibers can be attacked by corrosive media. Rubber based alternatives suffer at temperatures above 120 – 150 °C and chemical compatibility is not as broad as for fluoropolymers. Considering pump lined components, the alternative material proposed in the Annex E, paragraph 2.15, aren’t suitable for temperatures higher than 150 °C and chemical compatibility is not as broad as for fluoropolymers. Given the motivation above, it is clear that: any of the alternative material specified for example in Annex E 2.15, that should be used to substitute fluoropolymers as materials for lined components or gaskets, present an increased risk of leakage, premature failure or degradation of pump/gaskets components, causing hazardous, toxic or corrosive media release to the environment, with high risk also for personnel working with this machinery. Since at the time of writing there are no valid alternatives to fluoropolymers and it is not foreseen any big development in the very next years, the request is an exemption for fluoropolymers used in chemical processing plants equipment and pharmaceutical processing plant equipment. Banning fluoropolymers in chemical and pharmaceutical process industry will impair European capacity to produce intermediate products necessary constituents of all drugs actually on the market, moreover the dismantling of drugs, fertilizers and other chemical process plants, would lead to unemployment of more than 400 000 operators, considering also the supply chain and depriving Europe of a strategic sector. |

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| 3930 | Date:  2023/04/24 14:35  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  se cover GmbH  Org. country:  Germany | General Comments:  We work with ETFE as a cladding product in the construction industry. Such claddings last for 20 years and are emission free. ETFE is full recyclable at its life's end. Furthermore it represents a minor fraction of Fluoropolymer on the European market- Nevertheless should the PFAS be activated a complete industry in this area of construction / architecture in Europe will be annihilated and the same products will be eventually bought from non-European countries. |
| Answer to specific info request 1:  Architecture / Construction |
| Answer to specific info request 2:  We have minimum emmision as we need to dismantle the product and send it to a recycling facility. |
| Answer to specific info request 3:  The product will not be incinerated |
| Answer to specific info request 5:  Our company may use up to 20tons per year |
| Answer to specific info request 6:  Should PFAS be activated our entire company is in real danger to be shut down |
| Answer to specific info request 7:  Due to the minor impact of our use of PFAS and the major impact on our industry, we would appreciate a derogation for the use in the architectural / construction industry |
| Answer to specific info request 8:  We do not have alternative products |

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| 3931 | Date:  2023/04/24 17:21  Content:  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  ViscoTec Pumpen- und Dosiertechnik GmbH  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  protection of our commercial interests, including intellectual property, would be undermined | General Comments:  For many substances of the PFAS group a restriction is necessary without any doubt facing their well-known negative impact. However, with special regard to fluoropolymers, these materials are non-toxic, non-bioaccumulative, non-bioavailable and non-mobile in the aquatic environment, but there are many important applications for which so far, no alternative for these materials is known or presents an adequate substitute once they are applied under harsh conditions [1-2]. A couple of fluoropolymers and their use are crucial to achieve certain goals of the European society and hence, their unqualified restriction would rather cause high negative impact on the whole society and put the independence of Europe in danger than provide a risk reduction. Consequently, there should be an exemption for certain fluoropolymers needed in elemental applications where feasible alternatives are not expectable. The core competence of our company comprises highly specialized, miniaturized progressive cavity pumps, based on eccentric screw (rotor) and a rubber-based stator. The rubber is a key component for the pump principle (well known as the Moineau-principle). Such pumps are widely used in almost all production areas for goods of- modern daily life! From aerospace industry, wind turbine or solar panel fabrication, production of mobile devices, the car industry (especially electric vehicle, fuel cell, battery technology), food, medical or pharmaceutical production – all these sectors have the need of volumetric dispense pumps in their production where in most cases these pumps and dispensers are indispensable . For some applications, the stator material can be chosen from non-fluorinated materials (we use them wherever possible), but currently most applications require a high-performance stator either made from poly- (FKM, FEPM) or perfluorinated elastomer (FFKM) due to its outstanding chemical resistance required under harsh conditions (predominant case for most customers). Likewise, our sensors (also FFKM) and most gaskets and hose linings (PTFE) as well as greases (PTFE) and protection foils (ETFE) are made from fluoropolymers. Moreover, some of our pump housings made of stainless-steel need additional protective anti-stick coating which is currently also a fluorinated polymer coating. Our pumps and peripheral devices are widely used to dispense abrasive and chemically aggressive media, e.g. organic solvents, acids and bases, or acrylic based adhesives, paints, soldering pastes and sealants as well as cosmetics, or sauces, flavors etc. in the food and pharmaceutical industry. All bonding applications – which are also required to produce e.g. catheters, pacemakers or respiratory masks – need to be supported by volumetric dosing pumps. Since prospectively there is no alternative material which provides the excellent chemical and thermal resistance of certain fluoropolymers along with the required mechanical properties (applies particularly to fluoroelastomers), many of our customers would no longer be able to perform their applications. Consequently, at least 90% of all our customers (about 3500 worldwide and approx. 900 in Europe) would be directly affected, and we would have to cut about 150 jobs (approx. 55% ) while facing sales losses of approx. 40-60 million euros . On the other hand, the total tonnages of fluoropolymers we apply are less than 1 t/a without causing any traceable PFAS emissions to the environment. Hence, we find that a full restriction of these fluoropolymers in almost all technical applications would be in no relation to the highly negative socio-economic consequences. Thus, we request for an exemption for certain technically important fluoropolymers applied in such low amount, since these polymers entail a rather low risk to human health and the environment. This must be clearly distinguished from other PFAS which are dangerous and/or rather easy to replace. Nonetheless, we see the big problem of persistent materials and regarding recycling, we plan to offer a recycling strategy to our customers where we take care of the end-of-life phase of the employed fluoropolymers to ensure an eco-friendlier life cycle.  Literature sources: [1] B.J. Henry et al., Integr. Environ. Assess. Manag., 2018, 14, 316-334. [2] S.H. Korzeniowski et al., Integr. Environ. Assess. Manag., 2023, 19, 326-354. |
| Answer to specific info request 1:  Food contact materials and packaging – Industrial food and feed production Lubricants – Sector as a whole |
| Answer to specific info request 5:  - Paragraph 5 (s) lubricants used under harsh conditions: PTFE-based greases are used in our pump systems (less than 0.1g per pump) to protect our shaft sealing rings and gears from aggressive media (acids, solvents, etc). We apply less than 2kg per year and since the grease is firmly installed inside the pump with very little contact to media the emission to environment is negligibly low. We can say this since even after many 100k of runs and after years in use the grease is still present inside the pump. - Paragraph 6 (a) food contact materials: Some of our pump systems are used in food production (e.g., to apply tomato sauce onto the pizza) and there we need the fluoropolymer FFKM as stator and seal material, since – to our knowledge – it is the only material which withstands the harsh cleaning cycles applied in hygienic area (20% NaOH, organic acids, special solvents, steam at temperatures up to 140 °C and autoclavation). The tonnages we need are less than 10 kg per year! Moreover, there are no PFAS emissions which we can attribute to this FFKM rubber which is a vulcanized polymer material. |
| Answer to specific info request 6:  Fluoropolymers: Thermoplastics and rubber/elastomer used in gaskets, stator material, O-rings, protective foils, shaft seals, sensor membranes, hose linings, anti-stick protective coatings – wherever the material needs to withstand very harsh conditions. In our case: materials needed to produce our pumps, dispensers, emptying systems, fluid supply and treatment systems and sensors. (a) PTFE, ETFE, PVDF and FKM, FEPM, FFKM rubber: tonnages in total less than 1t/a and well below 0.5t/a in Europe and without identifiable PFAS emissions during our rubber and pump production or use. (b) Excellent chemical resistance and inertness, high temperature resistance, bio-resistance, and resistance against degradation by hydrolysis. In the case of elastomer additionally: mechanical properties (elasticity, abrasion resistance, etc.) required in a stator of a progressive cavity pump used under harsh conditions. To demonstrate the benefits of fluoroelastomers we have attached the results of some chemical resistance tests with different materials (see confidential attachments). (c) All companies in this sector would be directly affected: approx. 15 firms ; and almost all the customers (in our case globally approx. 3500 companies and about 900 in Europe, B2B only; plus, many customers of our competitors). (d) So far, there are no alternatives available on the world polymer market which can adequately replace fluoroelastomers (especially not the FFKM rubber) and only few alternative high-performance materials which can be used in seal applications (e.g. gaskets) like PEK/PEEK are available. Wherever possible, we try to use such an alternative. (e) Since 2016, we have been actively looking for alternative materials and recently a 10-month research project starting from 02/2022 with an investment of about 10,000 Euros was focusing on thermoplastic elastomers (TPEs). However, the materials were unable to achieve sufficient resistance against chemical attack while providing the required mechanical properties. The achievement of these two requirements are the major challenges in finding alternatives, especially for the fluoroelastomers. Therefore, we are strongly dependent on the elastomer market and the availability of feasible materials which are currently not foreseeable. Moreover, once an alternative elastomer becomes available, we would need to re-evaluate and properly adjust our dosing systems since their reliability and precision is crucial to our customers. For this, we expect another 2-5 years of R&D until market introduction and another 1-3 years for our customers in their individual evaluation processes with 2-3 years in the area of food and pharma applications. (f) Currently the substitution potential cannot be adequately estimated. (g) In contrast to many other PFAS, the impact of a restriction on fluoropolymers would strongly affect all companies and sectors where these high-performance materials are irreplaceable at present. As a result, consumers as well as the whole European society would be negatively affected once certain products and key technologies would cease and significant losses of jobs and growth would become reality. In certain cases, a persistent material is required to withstand the operating conditions and any alternative material would also need to be persistent to fulfill this criterion. This is more a question about proper end-of-life management. As an example, one of our customers applies our pump systems to dose the right amount of firefighting foam into the extinguishing water in fire-fighting vehicles. To withstand this concentrate, a FEPM elastomer and PTFE seals are used inside the pump. Moreover, another two customers apply acrylate-based adhesives in the production for medicinal products such as masks or catheters where only FFKM elastomer was acceptably resistant against the acrylates. To produce solar modules, another customer needs our dosing pumps for grouting the junction box and uses a silicone rubber where the hardening component very aggressively attacks our stators. We have tested several materials but only a FFKM elastomer was applicable (see confidential attachments). These are only a few examples where our products make a significant contribution to key European industries from which the whole European society benefits. |