**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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| 8256 | Date:  2023/09/21 15:36  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:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The document includes data (quantities) that should be protected to avoid to undermine our commercial interests. | General Comments:  As a vacuum technology company, we do not use PFAS directly in our manufacturing process as a raw material. However, PFAS are widely present in components that we use: lubricants, sealings, electronics. PFAS are needed due to the properties they provide, and there are currently no alternatives to PFAS that meet the harsh requirements of vacuum applications. This makes FKM/FFKM/PFTE/PFPE irreplaceable for the vacuum industry. There are many key products that require vacuum and therefore PFAS in their manufacturing process (e.g., all semiconductor components, pharmaceutical products, batteries for electromobility, nuclear industry, solar panels, …) and while the final products do not contain PFAS, they could not be manufactured without vacuum and therefore without PFAS.  PFAS are included in vacuum pumps for three different usages: 1. In sealing components used in all pumps: Sealings/Gaskets/O-rings/Shaft seals made of fluoropolymers (including FKM, FFKM, PTFE especially) are used in vacuum pumps, vacuum valves, vacuum pipeline assembly and other vacuum devices (gauges, leak detectors,…). Why are there Fluoropolymer Sealings/Gaskets/O-rings/Shaft and tip seals in vacuum pumps? As a general statement, sealing is essential as soon as vacuum is involved. It provides tightness and prevent external atmospheric air to degrade the produced vacuum, and it prevents process gases – possibly harmful – involved under vacuum to leak and potentially exit the vacuum area. There are a lot of these applications where the use of traditional elastomers (such as EPDM, NBR) is ruled out. Aggressive chemicals, extreme temperatures or only ageing can destroy conventional O-rings. This ultimately leads to leakage and may lead to environmental and worker safety issues. There is no adequate replacement for the fluoropolymers used, and it is unlikely to be, due to strength requirements on the material itself. Fluoropolymers have an extremely high price and are only used where no other solutions are available. 2. PFPE oil or grease for specific applications Perfluoropolyether (PFPE) oil or grease have a very low outgassing compared to other fluids (vapour pressure of 6×10−8 Torr), which is extremely valuable for vacuum applications. PFPE also withstand the harsh conditions (heat, chemicals, solvents, corrosion, toxicity, flammability, etc.) that are needed in the industries of chemical, electronic, cosmetic, machinery, aerospace, nuclear, etc. This combination of properties (low outgassing and resistance to harsh environment) are mandatory for vacuum applications, and there is currently no alternative (known or foreseen) for PFPE in these applications. 3. PFAS used by our suppliers in electronic and electromechanical products or related components The amount of PFAS in these kinds of components is low and shall be submitted by the sub-sector of electronic and electromechanical suppliers. We will focus on the sealings and PFPE that are directly involved in the vacuum technology.  The proposal for restriction as it is, will lead to major impact on all the listed applications, also creating a major distortion of commercial and industrial competition with countries without restrictions. We request full exemption (with regulation and control) for manufacturing and recycling of the following fluoropolymers (FKM, FFKM, PTFE, PFPE) from the restriction proposal, for use in the vacuum pumps, vacuum valves, vacuum pipeline assembly and other vacuum devices. Exemption for “Vacuum technology and its machines and components” as a main application would be better and more comprehensive. Rather, it is correct to ban specific processes and procedures that lead to environmental damage. The restriction should focus on large number uses (such as manufacture, TULAC, food contact material, …), where the manufacture, use and end-of-life phases emit massively into the environment. |
| Answer to specific info request 1:  Our sector is not included in Annex XV (table 9), please see further information attached to info request 6. |
| Answer to specific info request 2:  Please see further information attached to info request 6. |
| Answer to specific info request 3:  Please see further information attached to info request 6. |
| Answer to specific info request 5:  Please see further information attached to info request 6. |
| Answer to specific info request 6:  Please see annex attached in Section V. |
| Answer to specific info request 7:  Please see further information attached to info request 6. |
| Answer to specific info request 8:  Please see further information attached to info request 6. |
| Answer to specific info request 9:  Please see further information attached to info request 6. |

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| 8257 | Date:  2023/09/21 15:37  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Chemours Company  Org. country:  Belgium  Attachment:  <redacted>  Privacy statement:  CONFIDENTIAL DATA, COMMERCIAL INTERESTS | General Comments:  - |

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| 8258 | Date:  2023/09/21 15:36  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:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The documents includes data which should be protected to avoid to undermined our commercial interests. | General Comments:  As a vacuum technology company, we do not use PFAS directly in our manufacturing process as a raw material. However, PFAS are widely present in components that we use: lubricants, sealings, electronics. PFAS are needed due to the properties they provide, and there are currently no alternatives to PFAS that meet the harsh requirements of vacuum applications. This makes FKM/FFKM/PFTE/PFPE irreplaceable for the vacuum industry. There are many key products that require vacuum and therefore PFAS in their manufacturing process (e.g., all semiconductor components, pharmaceutical products, batteries for electromobility, nuclear industry, solar panels, …) and while the final products do not contain PFAS, they could not be manufactured without vacuum and therefore without PFAS.  PFAS are included in vacuum pumps for three different usages: 1. In sealing components used in all pumps: Sealings/Gaskets/O-rings/Shaft seals made of fluoropolymers (including FKM, FFKM, PTFE especially) are used in vacuum pumps, vacuum valves, vacuum pipeline assembly and other vacuum devices (gauges, leak detectors,…). Why are there Fluoropolymer Sealings/Gaskets/O-rings/Shaft and tip seals in vacuum pumps? As a general statement, sealing is essential as soon as vacuum is involved. It provides tightness and prevent external atmospheric air to degrade the produced vacuum, and it prevents process gases – possibly harmful – involved under vacuum to leak and potentially exit the vacuum area. There are a lot of these applications where the use of traditional elastomers (such as EPDM, NBR) is ruled out. Aggressive chemicals, extreme temperatures or only ageing can destroy conventional O-rings. This ultimately leads to leakage and may lead to environmental and worker safety issues. There is no adequate replacement for the fluoropolymers used, and it is unlikely to be, due to strength requirements on the material itself. Fluoropolymers have an extremely high price and are only used where no other solutions are available. 2. PFPE oil or grease for specific applications Perfluoropolyether (PFPE) oil or grease have a very low outgassing compared to other fluids (vapour pressure of 6×10−8 Torr), which is extremely valuable for vacuum applications. PFPE also withstand the harsh conditions (heat, chemicals, solvents, corrosion, toxicity, flammability, etc.) that are needed in the industries of chemical, electronic, cosmetic, machinery, aerospace, nuclear, etc. This combination of properties (low outgassing and resistance to harsh environment) are mandatory for vacuum applications, and there is currently no alternative (known or foreseen) for PFPE in these applications. 3. PFAS used by our suppliers in electronic and electromechanical products or related components The amount of PFAS in these kinds of components is low and shall be submitted by the sub-sector of electronic and electromechanical suppliers. We will focus on the sealings and PFPE that are directly involved in the vacuum technology.  The proposal for restriction as it is, will lead to major impact on all the listed applications, also creating a major distortion of commercial and industrial competition with countries without restrictions. We request full exemption with regulation and control for manufacturing and recycling of the following fluoropolymers (FKM, FFKM, PTFE, PFPE) from the restriction proposal, for use in the vacuum pumps, vacuum valves, vacuum pipeline assembly and other vacuum devices. Exemption for “Vacuum technology and its machines and components” as a main application would be better and more comprehensive. Rather, it is correct to ban specific processes and procedures that lead to environmental damage. The restriction should focus on large number uses (such as manufacture, TULAC, food contact material, …), where the manufacture, use and end-of-life phases emit massively into the environment. |
| Answer to specific info request 1:  Our sector is not included in Annex XV (table 9), please see further information attached to info request 6. |
| Answer to specific info request 2:  Please see further information attached to info request 6. |
| Answer to specific info request 3:  Please see further information attached to info request 6. |
| Answer to specific info request 5:  Please see further information attached to info request 6. |
| Answer to specific info request 6:  Please see annex attached in section V. |
| Answer to specific info request 7:  Please see further information attached to info request 6. |
| Answer to specific info request 8:  Please see further information attached to info request 6. |
| Answer to specific info request 9:  Please see further information attached to info request 6. |

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| 8259 | Date:  2023/09/21 15:42  Content:  Hazard or exposure  Environmental emissions  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Lubricants. We have previously submitted our response for time-unlimited derogation of PFPE (Perfluoropolyether) oils Lubrication application. In our submission, we meticulously outlined the essential uses of PFPE oils and delineated their socio-economic impacts. Furthermore, we substantiated the claim of our products being PFAS (Per- and Polyfluoroalkyl Substances) free with comprehensive evidence. Within the end-of-life cycle section, we expounded upon our assertion that PFPE oils undergo complete decomposition under standard operating conditions for municipal and industrial waste incineration, which typically range from 850°C to 1100°C. We have, in support of this claim, conducted a pyrolysis Gas Chromatography-Mass Spectrometry (GC-MS) analysis in our laboratory. Please find attached document for details. |

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| 8260 | Date:  2023/09/21 15:42  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Due to the special properties of PFAS as required for the food production sector, possible alternative materials will also be similarly problematic as PFAS in terms of their end-of-life properties, which greatly reduces the prospect of technically comparable alternatives.  The restriction proposal targets specific chemical properties of PFAS. It can be assumed that, based on basic chemistry, it will not be possible to bring similar materials with these properties to application. We see no prospect of alternatives with this performance in terms of safe food production (Food and Dairy). Safety in food production competes with the goals of the PFAS restriction ban in this regard and requires special regulations.  We strongly recommend that the end-of-life phase for sealing rings and valve components containing PFAS needs to be considered in a very differentiated way, especially for the industrial food production sector for highly sensitive consumer goods.  We refer to the position paper of the VDMA " PFAS restriction under the REACH Regulation". |
| Answer to specific info request 1:  Industrial food and feed production |

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| 8261 | Date:  2023/09/21 15:43  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment: | General Comments:  See attachment |
| Answer to specific info request 1:  See attachment |
| Answer to specific info request 2:  See attachment |
| Answer to specific info request 3:  See attachment |
| Answer to specific info request 4:  See attachment |
| Answer to specific info request 5:  See attachment |
| Answer to specific info request 6:  See attachment |
| Answer to specific info request 7:  See attachment |
| Answer to specific info request 8:  See attachment |

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| 8262 | Date:  2023/09/21 15:51  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |

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| 8263 | Date:  2023/09/21 15:56  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  AIAD - Federazione Italiana per l'Aerospazio, la Difesa e la Sicurezza  Org. country:  Italy  Attachment: | General Comments:  As member of ASD (Aerospace, Security and Defence Industries Association of Europe) , AIAD contribute and fully support the Dossier on PFAS Restriction presented by ASD during the ECHA pubic consultation. Please refer to the Position Paper attached. |
| Answer to specific info request 1:  Please refer to the Position Paper attached. |
| Answer to specific info request 6:  Please refer to the Position Paper attached. |
| Answer to specific info request 7:  Please refer to the Position Paper attached. |
| Answer to specific info request 8:  Please refer to the Position Paper attached. |

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| 8264 | Date:  2023/09/21 15:56  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Access to documents would undermine the protection of commercial interests of a legal person, including intellectual property. | General Comments:  - |

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| 8265 | Date:  2023/09/21 15:59  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Confidential treatment should be granted to the uploaded Confidential Attachment, and any future access to document request should be refused, (1) for the protection of the company’s commercial interests, including its intellectual property, and (2) for the protection of personal data and privacy, pursuant to Article 4(2) of Regulation (EC) No 1049/2001 (the “PAD Regulation”). In the absence of a definition of ‘commercial interests’ in the PAD Regulation, the Court of Justice of the EU has confirmed that, for example, information on company methods and know-how, and elements of business strategies are covered by a general presumption that their disclosure would in principle undermine the protection of commercial interests of the company (Case T-651/21, Hans-Wilhelm Saure v Commission, EU:T:2022:526, paragraphs 106 and 107). In this case, the Confidential Attachment contains confidential information, trade secrets and proprietary data that are not available in the public domain. Specifically, the document contains information such as, inter alia, (i) detailed data on the company’s product (including product name, production process, physicochemical properties, alternative technologies and product lifecycle information) and (ii) a proprietary study on the performance of alternatives produced by differing technologies. This expertise and know-how are not publicly available and its disclosure would cause significant harm to the competitive position of the company as it would undermine its commercial interests, including intellectual property rights. Indeed, knowledge of such information could allow third parties such as an applicant for public access to documents to discover the proprieties and composition of products manufactured and placed on the market by the company, as well as the company’s commercial strategy, which could ultimately undermine the commercial interests of the company. The Confidential Attachment also contains the names and signatures of the authors of supporting documents, as provided by testing laboratories and consultants. These data constitute personal data, therefore this request must be assessed in light of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (“Regulation (EC) No 2018/1725”). In accordance with Article 1 of Regulation (EC) No 2018/1725, it falls on the EU Institutions and bodies to protect the fundamental rights and freedoms of natural persons, in particular the right to privacy with respect to the processing of personal data. Names and signatures constitute such personal data, and should not be disclosed. Confidential treatment should consequently be granted to the uploaded document in application of the exception to disclosure contained in Article 4(2), first indent of the PAD Regulation. | General Comments:  This information request is addressed in the confidential attachment. |
| Answer to specific info request 1:  This information request is addressed in the confidential attachment. |
| Answer to specific info request 2:  This information request is addressed in the confidential attachment. |
| Answer to specific info request 5:  This information request is addressed in the confidential attachment. |
| Answer to specific info request 6:  This information request is addressed in the confidential attachment. |
| Answer to specific info request 8:  This information request is addressed in the confidential attachment. |
| Answer to specific info request 10:  This information request is addressed in the confidential attachment. |

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| 8266 | Date:  2023/09/21 15:58  Content:  Scope or restriction option analysis  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  G. Pohl-Boskamp GmbH & Co. KG  Org. country:  Germany  Attachment:  <redacted>  Privacy statement:  We refuse access to this document because disclosure would undermine the protection of commercial interests of a legal person, including intellectual property. Article 4(2) of Regulation (EC) No 1049/2001 | General Comments:  Polymeric perfluorinated and polyfluorinated alkyl substances (PFAS) are indispensable for pharmaceutical production plants and the manufacture of drugs  Polymeric PFAS are used in the pharmaceutical production due to their chemical properties (high resistance to mechanical stress, temperature and aggressive substances like acids and alkalis, very low chemical reactivity). The great advantage is that they do not react, or react only to a negligible extent, with potential reaction partners under the given conditions. This makes them the ideal and not exchangeable material for seals, valves, coatings, hoses, rotor plates, lubricating oils, membranes, sterile filters, films or film distributors – summarized everywhere there is contact with the product in the production facilities or with consumables. For the foreseeable future the pharmaceutical industry is dependent on these materials in their production facilities.  For instance, PFAS encounter the following gases and substances without any chemical reactions taking place:  • Ozone (important component in production for high quality water for drugs)  • Pure steam and plant steam (temperature appr. 140 °C)  • Sodium hydroxide (Purification)  • Citric acid (Purification)  Substitution is not trivial  Currently there are no alternative substances despite intensive research. It is also unknown whether manufactures of the individual plant components will be able to develop PFAS- free alternatives at all, that meet the requirements of current PFAS-containing plant components. However, there is no doubt that plant components with precisely these "PFAS properties" are urgently needed for the construction and operation of safe and process-optimized industrial plants - so as things stand today, there is still no substitute.  Therefore, substitutions in chemical-pharmaceutical production plants are not trivial either, which will be exemplified by the following example "alternative membranes":  • PFAS are resistant to hot (above 60°C) and thus particularly aggressive acids. Alternatives, for example membranes made of ethylene-propylene-diene-monomer rubber (EPDM) would decompose in a very short time, although they are said to be largely resistant to chemicals.  • In addition, the alternative use of EPDM membranes would involve the risk of EPDM particles getting into the product, which must definitely be ruled out in the pharmaceutical industry.  • Furthermore, during steam generation EDPM-membranes would very quickly become brittle, dissolve, and become dispersed in the system.  • In addition, the use of EPDM materials would cause valve seals to leak quickly, posing a significant product risk as well as a high safety risk.  Polymeric PFAS, first and foremost PTFE, are used due to their reaction inertia. Therefore, they are a component of material that is in direct contact with the active drug. This not only guarantees the greatest possible safety of the drug, but also the occupational safety of the medical staff, especially when administering highly effective drugs (e.g., immunotherapeutics).  Consequences of any substitutions  Even if a successful substitution of used and established PFASs were to succeed, it would pose major challenges to manufacturers:  • Suitability testing of alternative materials: Pharmaceutical entrepreneurs must meet regulatory requirements for the materials in contact with the product or components of excipient or the product itself. These various requirements are very specific to produce drugs and active ingredients based medicinal products (GxP; ICH; MDR). New Materials have to undergo a very lengthy proficiency test. In addition, new materials may not be used in production until the dossiers for marketing authorization or registration documents have been approved by the authorities or notified bodies. Pharmaceuticals are also subject to extensive clinical trials. It must be ensured that the drug with, for example, a modified excipient is safe, effective, and pharmaceutically harmless for patients.  • Validation of the use of alternative materials PFASs are used, for example, as adhesive protection on the inside of tubes used to fill liquids into primary packaging, as well as in mass production. When replacing the tubes material, it would then have to be demonstrated that no contamination of the new tube material diffuses into the liquid and vice versa. The resulting very lengthy and bureaucratic effort for new validations and analyses would be enormous, very costly and disproportionate.  Consequences of any prohibition  PFAS are used as active ingredients, but also as important raw material, precursor, additive, and excipient during production of active ingredients, as well as in medicinal products. Both the production and use as well as plant engineering aspects must be considered. Without clearly described exceptions, the situation could arise where substances excluded from the restriction or prohibition are permitted but their manufacture within the EU is prohibited. This would mean that relevant substances could only be imported from non-European countries. Examples include active pharmaceutical ingredients that are essential and critical to the treatment of diabetes, cancer, multiple sclerosis and rheumatism, among others, and that are currently still manufactured in the EU or in Germany and serve to supply the European healthcare system. This would then no longer be possible. The consequence would be that the relevant production facilities would be closed, jobs in the EU would be lost, currently planned investments in the EU could not be realized, and the active pharmaceutical ingredients would have to be imported from non-EU countries - here in particular from Asia (especially China and India) - which would further increase the critical dependence of the European healthcare system on these imports.  Furthermore, a comprehensive and radical prohibition of PFASs in production facilities and productions equipment and consumables, there is an immediate and real risk that the manufacturers of such PFAS-containing equipment (e.g., sealing rings, sterile filters, liquid distributors in short-path distillation, product-contacting filter membranes in active ingredient production, mechanical seals on the rotors of liquid-liquid chromatography in the purification of active ingredients) would no longer produce and sell in the usual quantities. Production would also be discontinued for economic reasons. In case of maintenance, for example, these components would no longer be available. If there are (then) also no alternatives, there would be a standstill of the production facilities.  The high risk of discontinuing production and all the consequences described above would also affect packing material from drugs (e.g., blister foil). Thus, the manufacture and availability of pharmaceuticals, and thus patient care, would be directly affected, even though an exemption is provided per se for the active ingredients themselves in the restriction proposal. It should also be noted that the proposed exemptions should be considered on a case-by-case basis. For example, medicinal propellants ((HFC 134c und HFC 227ea), the proposed 18-month period is neither technically nor economically feasible for affected companies and would equally jeopardize patient care in Europe and beyond.  It should also be considered that the radical nature of the Restriction Proposal hinders innovation. It cannot be ruled out that highly effective active pharmaceutical ingredients containing two or three fluorine atoms (i.e. a fluorinated methylene group or a fluorinated methyl group) will be developed in the future. The ban is therefore a relevant interference in the free economic development of companies in the European Union and a preferential treatment of companies outside the EU. It is almost paradoxical that the substances then declared as active pharmaceutical ingredients would be allowed to be imported into the EU.  In summary, the proposed restriction increases the risk of a migration of the pharmaceutical industry to less strictly regulated regions and existing products (drugs or combination products) with long-standing approvals disappear from the market (without replacement).  Polymeric PFAS in laboratory equipment  The restriction proposal comprises a derogation with a 12-year transition period for diagnostic laboratory equipment. Diagnostic laboratory equipment is related to the examination of biological material in the context of human (or veterinary) medicine.  However, normal laboratory equipment, especially the equipment of analytical laboratories, is equally based on the use of (polymeric) PFAS. The properties already mentioned in connection with production equipment make materials such as PTFE an indispensable component of analytical equipment. The further the determination limits are lowered, for example in environmental analysis, the more the analyst is dependent on there being no contamination of the sample solution. PTFE is ideal and irreplaceable for this.  Polymeric PFASs, especially PTFE, are also used in pharmaceutical analysis. Since the analytical methods are part of the approval documentation, they cannot be changed without further ado. Less accurate and safe methods are not accepted by regulatory authorities in view of the advanced state of the art.  Overall, the preference for diagnostic laboratory equipment over "ordinary" laboratory equipment is not comprehensible. Therefore, the exemption for diagnostic laboratory equipment should be extended to laboratory equipment (in general).  Admissibility of the scope of the Restriction Proposal  It is seriously doubted that polymeric PFAS may be banned in the same way as other (small molecule) PFAS. Polymers such as polytetrafluoroethylene (PTFE) are not only used because of their exceptional technological position but also because of their toxicological harmlessness. It therefore seems in no way justified to ban them on the basis of toxicological properties of other - only distantly related - molecules. The fact of slow biotic degradation and the resulting concerns about accumulation in biological systems such as soils also does not justify this. It should be noted that there are no data in annexes of the restriction proposal indicating that PTFE accumulates in biological systems. Also in other European reports, such as HBM4EU or the data on PFAS in waters, PTFE is not listed as a substance group. It is therefore doubtful whether PTFE, like other PFAS subgroups, accumulates in biological systems. The mobility in water mentioned in the justification of the Restriction Proposal does not apply to polymeric PFAS anyway. If, despite these considerations, PTFE and other fluorine-containing polymers were to be banned, we believe that a permanent exemption would be possible if a take-back system for the polymers used in industrial plants prevented them from entering the environment.  These considerations also apply to the other end of the scope of the Restriction Proposal: It is seriously doubted that molecules containing two or three fluorine atoms (with a possible molecular weight of several 100 daltons) have the same (environmental) toxicological properties as, for example, a perfluorooctanoic acid, the use of which is already rightly restricted today.  In general, it will have to be clarified whether properties of individual molecules may lead to a ban of an arbitrarily defined group of substances to the extent now planned. We fear that if the Restriction Proposal is implemented, there will be legal uncertainty for many years due to ongoing lawsuits. It is precisely this kind of legal uncertainty that poses a risk to medium- sized companies, as they cannot relocate production to other EU countries in the same way as multinational corporations and, if necessary, bring it back after clarification. Reference is made here to the current legal uncertainty surrounding the use of titanium dioxide in pharmaceuticals.  It must also be ensured that existing ordinances and regulations are observed in order to rule out overregulation. The existing European F-Gas Regulation (517/2014) already comprehensively regulates HFCs. Currently, this regulation is under revision. This will ensure that HFC 134a and HFC 227ea are phased down (in line with the Kigali Amendment to the Montreal Protocol). Currently, two next-generation propellants are under development: HFC 152a and HFO 1234ze. HFC 152a is not subject of the PFAS consultation. It is important that any PFAS restrictions are consistent with the F-Gas Regulation.  We demand: Adjustment of the restriction proposal  In order to maintain the security of supply of medicinal products and substance- related medical devices from European production and manufacture, targeted open-ended exemptions from the restriction should be provided for the uses listed above:  • In the event that polymeric PFASs are not generally removed from the Restriction Proposal due to their toxicological harmlessness, PFAS-containing equipment parts in industrial plants including the necessary supply chain should be excluded. Pharmaceutical production plants contain countless components containing PFAS (spare parts, wear parts, used parts), which cannot simply be replaced for the above reasons. It is therefore imperative to implement unlimited exemptions for all PFAS- containing components in pharmaceutical production facilities.  • Consumables for the production of pharmaceuticals The production of pharmaceuticals requires, among other things, a wide variety of consumables (e.g., sterile filters). These are currently also manufactured in Europe. It is therefore imperative to implement unlimited exemptions for all PFAS-containing consumables that are mandatory to produce pharmaceuticals. This also serves the sustainability and economic viability of industrial plants.  • Intermediates and precursors for the manufacture of pharmaceuticals The indefinite exemptions proposed in the restriction proposal relate to the active ingredients themselves and do not cover their manufacturing process. It is therefore imperative that exemptions be implemented for all PFAS-containing substances, their intermediates and processing aids required in the manufacturing process of medicinal products.  • The derogation for diagnostic laboratory equipment should be extended to laboratory equipment (in general). |
| Answer to specific info request 1:  While such a socioeconomically negligible sector as “skiwax” was examined in great detail, the much more relevant industrial sector, especially the chemical and pharmaceutical industry has been neglected. Pharmaceuticals have been covered as far as active ingredients fulfilling the PFAS definition are concerned. But the use of PFAS in industry, where the output of production is not a PFAS, seems to have been forgotten. This might also apply to other sectors when PFAS are only used in production and are not contained in the finished products. Diaries and other food processing facilities may serve as examples. While mentioning diagnostic laboratory equipment, the sector of analytic services (as a whole) is missing. PFAS are used in any laboratory, independent from the fact whether the analysis is diagnostic or not. Analysis of pharmaceutical raw materials (actives and excipients), intermediates and finished products is given as an example. See more details in the confidential part! |
| Answer to specific info request 6:  See confidential statement |

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| 8267 | Date:  2023/09/21 16:00  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Innovatec Gerätetechnik GmbH  Org. country:  Germany | General Comments:  In the context of electrolytic PEM ozone generators for pure water production and storage, the use of a few fluoropolymers and fluorinated ionomers cannot be avoided. Due to the anodic evolution of hydroxyl radicals, ozone and other reactive oxygen species, an ionomer with an extraordinary (electro-) chemical resistance is required and the scientific literature does not indicate any substance class that would be able to cope with such harsh conditions except for fluorinated ionomers such as Nafion™. In order to provide pure water for the semiconductor and pharmaceutical industry, the use of highly oxidative-resistant construction materials in aqueous media is required. We therefore intentionally source fluorinated polymers (PTFE, FEP, FKM, Nafion™) without any processing except for PTFE and value them for the following reasons:  - Extremely high resistance to radical species, ozone and other reactive oxygen species - Hygienic low-friction material avoiding microbial adhesion - High resistance to gas permeability (safety issue) - Low electrical resistance (efficiency) - Long-term mechanical stability contributing to longer part lifetimes  As the selected construction materials are used in a closed, clean environment, an even partial release of PFAS as degradation products is avoided due to strict regulations derived from international pharmacopoeia. A re-use or recycling of the produced parts has already partially implemented in our company.  We apply for the exclusion of the substances mentioned (Fluoropolymers, fluorinated ionomers and highly fluorinated sealing materials) from the PFAS ban, as there are no alternative materials both in research or production. |
| Answer to specific info request 1:  In the Annex XV restriction report (Table 9), we do not find our products represented. In the area of semiconductors and electronics, we do find hints given for PEM fuel cells, which differ in their operation compared to PEM electrolyzers. Membranes used in fuel cells can be operated under moderate conditions and allow for a substitute material known from current literature. In contrast to that, the mentioned PEM electrolyzers intentionally produce larger amounts of oxidants which are known to rapidly disintegrate any known membrane materials except for poly- or perfluorinated ones. We apply for the inclusion of PEM electrolyzers onto a list of derogations. |
| Answer to specific info request 2:  During the production of ozone generators, several (per-)fluorinated compounds are processed. In total, the mass of all fluorinated materials makes up approx.. 300 kg/a: PTFE: Main compartment of electrolysis cell: subtractive manufacturing, valued for chemical resistance and electric isolation. FKM/FEP: Sealants requiring the same high chemical resistance in a pressurized and oxidative aqueous environment. PEM/Nafion™: As a core material, this ionomeric membrane serves as the solid electrolyte in the water purification process that can withstand the in situ produced and highly concentrated, reactive oxygen species. During manufacturing, PTFE is used as a pre-material and subtractively processed. Waste emerging during this process is collected and disposed by a specialized waste disposal company. The aim is to prevent any release into the environment. During use, emissions from the manufactured products are below the limits given by international pharmacopoeias. (Pharmacopoea Europaea, United States Pharmacopeial Convention, Japanese Pharmacopoeia). End-of-life phase: Fluorinated components are collected for an intended re-use or recycling process. In direct marketing for product distribution, this has already been implemented. Regarding fluorinated components from products sold by distributors/intermediaries, the responsibility for the accurate disposal is currently left to the end consumer. |
| Answer to specific info request 5:  With the low tonnage mentioned in request 2, it is possible to beneficially treat large water volumes with the lowest possible usage of fluorinated construction materials As with industrial partners, a thorough return or recycling system is already being implemented, a tracking of the produced parts is possible and enables a correct disposal or even re-use. Concerning emissions, a strict PFSA ban would force pure water plants to return to hot water storage and sanitization which is inherently tied to enormous amounts of precious energy compared to the currently used, energy-efficient cold water storage. |
| Answer to specific info request 6:  a) 300 kg/a fluoropolymers, fluorinated ionomers, sealants (Innovatec alone) b) The polymer electrolyte membrane poses as the key component of the PEM electrolyzer for ozone evolution. At the anodic interface to catalytically coated electrodes, an especially harsh environment is produced to achieve significant amounts of dissolved ozone for the subsequent process of water purification. Reactive oxygen species (i.e. hydroxyl radicals) emerge during this process and affect all construction material nearby. As a result, the construction materials in an ozone-evolving PEM electrolyzer must be especially resistant against these extreme oxidative conditions. Accounting for the electrolytic part of the ozone evolution, the insulating properties of the materials are appreciated and constructively considered. c) In the field of electrolytic ozone production, only a few companies are directly affected by the PFAS ban concerning the production of ozone generators. However, a large branch of the entire industry and economy relies on the production and storage of sanitized process water. The specific value of ultrapure water is estimated to grow from 1.8 to 3.9 B USD annually (2021 – 2030) (Ultra-Pure Water Market: Information by Application (Cleaning, Etching, Ingredient), End-User Industry (Semiconductor, Pharmaceuticals, Power Generation), and Region – Forecast till 2030, Straits research https://straitsresearch.com/report/ultra-pure-water-market). d) In the past, the most widespread alternative for pure water storage was the so-called “hot storage” with water kept at 75°C. Nowadays 20°C cold water is doped with up to 50 µg/L ozone as “cold storage”, consuming orders of magnitude less energy. Due to the currently tense situation in energy supply, wasting unnecessary amounts of precious energy is unfavoured and the cold storage is preferred. Additionally, ozone is also the disinfectant of choice whenever other chemicals (e.g. chlorine) cannot be introduced into processes for various reasons. e) At the current state of R&D, no other chemical class of materials except for fluorinated materials provide a sufficient resistance to the harsh oxidative environment while sustaining a suitable ion conductivity that is required in the extreme conditions of electrolytic ozone generation. Current research evaluated the most promising substitute materials that are perfectly fine for fuel cells with the conditions that emerge during water electrolysis. The membranes degraded within hours (even in the absence of ozone) which shows that long term stability is the crucial part that cannot be resolved without the use of fluorinated membranes. Additionally, non-fluorinated membranes - which are often SPEEK-based - suffer from a comparably low conductivity at the desired, moderate temperatures of 20°C. (Salleh, Muhammad Taufiq, et al. "Stability of SPEEK/Cloisite®/TAP nanocomposite membrane under Fenton reagent condition for direct methanol fuel cell application." Polymer Degradation and Stability 137 (2017): 83-99.), Sarirchi, Somayeh, Soosan Rowshanzamir, and Foad Mehri. "Simultaneous improvement of ionic conductivity and oxidative stability of sulfonated poly (ether ether ketone) nanocomposite proton exchange membrane for fuel cell application." International Journal of Energy Research 44.4 (2020): 2783-2800. f) N.a. g) A PFAS ban without the derogation for PEM electrolyzers would lead to an immediate end of the electrolytic ozone generation for process water sanitization. In consequence, cold water storage cannot be applied in the future and will have to return to highly energy consuming sanitization processes. This in turn would also lead to increased production costs resulting in a migration of industrial plants to other, non-regulated countries. However, the migration of high tech companies would hold against the EU’s aims and strategies to de-globalize supply-chains which was a direct result from the global economic crisis during the COVID-19 pandemic. For this exact purpose, agreements such as the European Green Deal und European Chips Act were signed. A restriction and ban on PFAS in the current version would negatively affect these agreements. By a sensible and deliberate use of PFAS in certain applications, the emission into the environment can be successfully avoided or at least reduced to a minimum by the implementation of e.g. return and recycling processes. This ecological aspect would be enabled by the addition of PFAS in PEM electrolysis applications onto the derogation list. |
| Answer to specific info request 8:  In the current proposal, PEM electrolysis as a whole is not considered and therefore not listed in Table. 8. As stated in the sections above, there is no perspective for a substance class that may replace fluorinated ionomers in the future in the application of PEM electrolyzers, especially intended for ozone evolution. We consider a derogation for PFAS in the context of PEM-based ozone generators justified, as small amounts of traceable and recyclable PFAS allow for a beneficial mass production of pure water in the various applications already mentioned. |

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| 8268 | Date:  2023/09/21 16:01  Content:  Scope or restriction option analysis  Hazard or exposure  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 1:  Sector: Medical devices (Annex E.2.9.) We request that: Product family sold items last 3 years ENT treatment units 400 Instrument storing cabinets 300 Suction unit, tracheal 24.000 Suction unit, transportable 21.000 Suction unit, surgical 5.500 Suction unit, thoracic 1.200 Suction unit, gas powered 1.000 Vacuum extractor, foetal 260 Suction unit, vacuum 5.000 Colposcope 120 ENT surgical microscope 270 Light source, endoscopic 340 Headlamp 190 Laryngostroboscope 330 Larygoscopes, rigid 450 Nasopharyngoscope 120 Endoscope video camera 240 Medical gas supply system 120 Medical gas supply system, component, terminal unit 5600 Valve, medical gas vacuum 600 Flowmeter, gas 800 Regulator gas, high-pressure 120 Balance test unis, vestibular stimulation 120 Irrigation kit, ear 90 Impedance Audiometer 65 Rhinomanometer 80 Oto-acoustic emission unit 35 Paranasal sinus ultrasound imaging system 12 Canister, suction unit, sterile 22.000 Drainage system, pleural, sterile 22.000 Surgical suction system collection container 29.000 Suction system filter, microbial 340.0000 Suction/irrigation tubing 32.000 Surgical pneumatic tourniquet sysem Cuff, tourniquet be newly added to derogation as missing uses. |
| Answer to specific info request 6:  As already stated in the general comments, the medical devices listed under 1. Sectors and (sub-)uses are very likely affected by a PFAS ban, as they consist of parts and materials listed in many other sectors covered in the Restriction Report e.g. electronics or coated metal parts. Missing these products will very likely lead to a discontinuation of the listed medical devices after a PFAS ban. Even when replacement materials for these parts and materials would be available at some point during a derogation period, we as a medical device manufacturer would have only the remaining time of said derogation period to engineer and validate the use within our medical devices. The current enforcement of the medical device regulation is very clear regarding the necessary proofs. We therefore request the exemption or at least the maximum derogation period of 12 years for the products listed under 1. Sectors and (sub-)uses on the basis of the negative impact on patient care if said medical devices would be no longer available due to the non- availability of necessary pre-products and the time-consuming revalidation after technical changes. |

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| 8269 | Date:  2023/09/21 15:59  Content:  Scope or restriction option analysis  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  FAMOT Pleszew Sp. z o.o.  Org. country:  Poland | General Comments:  First, thank you for giving us the opportunity to leave a comment on the restriction proposal. Because of their very good technical and chemical properties, Fluoropolymers are used as sealing and wiper products in the engineering and metalworking industry, and in the branch of the machine tool industry. As a producer goods industry, the machine tool industry products are delivered to many sectors like the Automotive sector, Medical, Food, Aerospace and Defense, and many more. Especially Fluoropolymers like PTFE and FKM are commonly regarded to meet the key internationally recognized safety criteria of the OECD for “polymers of low concern”. This means that they are chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile. For these reasons, fluoropolymers are also suitable, for example, as materials for food contact, in medical applications or in the production of high-purity active pharmaceutical ingredients (e.g., vaccines). At the end of its lifecycle an article made of PTFE or FKM, is recycled purposively and in a closed loop with incinerating. Even abrasions can’t get into the environment. The engineering and metalworking industry, as a huge sector, was not mentioned in the proposal. Therefore, many of our industrial applications for Fluoropolymers are not considered in the restriction proposal. With the prohibition of Fluoropolymers in the European Economic Area, the worldwide competitive ability will be reduced, as security relevant parts are affected. We demand from the competent authorities of the European Economic Area (EEA) to take over this scientific and simply reasonable approach. |
| Answer to specific info request 1:  Engineering and metalworking industry, machine tool industry. The Sector of the engineering and metalworking industry with the sub sector of machine tool industry was missing in the restriction proposal. |
| Answer to specific info request 6:  Backing rings based on PTFE for hydraulics in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,0164 t/a. About emissions no information is available. b. Using the part together with a high gliding functionality and a high chemical resistance (dry or oiled air, CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) there is no friction, meaning no micro particles can enter the environment. As Fluoropolymers such as PTFE or FKM have long chain "large molecules", recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If PTFE will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and physical properties (temperature range from -10 °C to 70 °C; pressure up to 250 bar, static use). Also, lower gliding properties reduce the efficiency of the machine and the machines' safety, resulting in rising energy consumption. Generally, thermoplastic backing rings are more difficult to assemble than the PTFE backing rings, leading to longer installation times. The alternative materials will have to fulfill the same technical and chemical requirements during the whole service live of the backing-ring. Spare parts for existing turning / milling machines will not be available anymore when the prohibition comes into place. Available alternatives will have a shorter lifetime. e. Searching for and testing of alternatives together with our suppliers will take five years or longer. f. A technically and economically feasible substitute is not available. g. Using alternative materials like thermoplastics leads to higher energy consumption due to more friction and to more frequent replacements meaning higher service costs for our customers. A lowered service life leads to higher service costs, and to higher production costs for our customers. With higher production costs, more frequent service intervals and lower technical specifications, our customers lose confidence in our products. This means a drop in orders and a reduction in jobs in the company. In the end, the costs for products through the supply chain for the end consumer also will increase. O-Ring / X-Ring seals based on FKM and FFKM for static hydraulic application in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,224554 t/a. About emissions no information is available. b. Using the part together with a high gliding functionality and a high chemical resistance (dry or oiled air, CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) there is no friction, meaning no micro particles can enter the environment. As Fluoropolymers such as FKM or FFKM have long chain "large molecules", recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If FKM and FFKM will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and physical properties (temperature range from 0 °C to 70 °C; pressure up to 250 bar, static use). Alternatives like NBR and HNBR elastomer-based seals have lower temperature limits and less chemical resistances. Especially the chemical resistance against coolants leads to a shorter lifetime of the seals. Also, lower gliding properties reduce the efficiency of the machine and the machines' safety, resulting in rising energy consumption. The alternative materials will have to fulfill the same technical and chemical requirements during the whole service live of the O-ring and X-ring-seals. Spare parts for existing turning / milling machines will not be available anymore when the prohibition comes into place. Available alternatives will have a shorter lifetime. e. Searching for and testing of alternatives together with our suppliers will take five years or longer. For the chemical resistance large in-depth studies are necessary. f. A technically and economically feasible substitute is not available. g. Using alternative materials like thermoplastics leads to higher energy consumption due to higher friction and to more frequent replacements meaning higher service costs for our customers. A lowered service life leads to higher service costs, and to higher production costs for our customers. With higher production costs, more frequent service intervals and lower technical specifications, our customers lose confidence in our products. This means a drop in orders and a reduction in jobs in the company. In the end, the costs for products through the supply chain for the end consumer also will increase. Preloaded O-Ring seals based on PTFE mixed with other materials for dynamic hydraulic applications in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,26557 t/a. About emissions no information is available. b. Using the part together with a high gliding functionality and a high chemical resistance (dry or oiled air, CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) there is no friction, meaning no micro particles can enter the environment. The preloaded O-ring seal has a material mix with an NBR-based O-Ring and an integrated PTFE backing ring, which is the gliding element for the rotatory or translatory movement. The PTFE backing ring also causes the preload for the O-Ring. As Fluoropolymers such as PTFE have long chain "large molecules", recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If PTFE will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and physical properties (temperature range from 0 °C to 70 °C; pressure up to 250 bar, dynamic use). Alternatives like single NBR or HNBR elastomer-based seals have lower temperature limits and chemical resistances. Especially the chemical resistance against coolants leads to shorter lifetime of the seals. Also, lower gliding properties reduce the efficiency of the machine and the machines' safety, resulting in rising energy consumption. The alternative materials will have to fulfill the same technical and chemical requirements during the whole service live of the O-ring-seals. Spare parts for existing turning / milling machines will not be available anymore when the prohibition comes into place. Available alternatives will have a shorter lifetime. e. Searching for and testing of alternatives together with our suppliers will take five years or longer. For the chemical resistance large in-depth studies are necessary. f. A technically and economically feasible substitute is not available. g. Using alternative materials like thermoplastics leads to higher energy consumption due to higher friction and to more frequent replacements meaning higher service costs for our customers. A lowered service life leads to higher service costs, and to higher production costs for our customers. With higher production costs, more frequent service intervals and lower technical specifications, our customers lose confidence in our products. This means a drop in orders and a reduction in jobs in the company. In the end, the costs for products through the supply chain for the end consumer also will increase. Radial shaft seals for high-speed rotatory applications in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,000567 t/a. About emissions no information is available. b. Using the part together with a high gliding functionality and a high chemical resistance (dry or oiled air, CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) there is no friction, resulting in no micro particles that can enter the environment. The radial shaft seal has a material mix with steel and PTFE or FKM. The PTFE or FKM part is the gliding element for the rotatory movement, while the steel stabilizes the form of the radial shaft seal. The PTFE sealing element protects the internal parts of the shaft from external influences and prevents leakages from one side of the seal to the other, while minimizing the friction of the seal within the rotary movement. As Fluoropolymers such as PTFE have long chain "large molecules", recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If PTFE and FKM will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and physical properties (temperature range from +10 °C to+ 70 °C; rotary speed up to 30.000 rpm). Alternatives like single NBR or HNBR elastomer-based seals have lower temperature limits and chemical resistances. Especially the chemical resistance against coolants leads to shortened lifetime of the seals. Also, lower gliding properties reduce the efficiency of the machine and the machines' safety, resulting in rising energy consumption. The alternative materials will have to fulfill the same technical and chemical requirements during the whole service live of the radial shift seal. Spare parts for existing turning / milling machines will not be available anymore when the prohibition comes into place. Available alternatives will have a shorter lifetime. e. Searching for and testing of alternatives together with our suppliers will take five years or longer. For the chemical resistance large in-depth studies are necessary. f. A technically and economically feasible substitute is not available. g. Using alternative materials like thermoplastics leads to higher energy consumption due to higher friction and to more frequent replacements meaning higher service costs for our customers. A lowered service life leads to higher service costs, and to higher production costs for our customers. With higher production costs, more frequent service intervals and lower technical specifications, our customers lose confidence in our products. This means a drop in orders and a reduction in jobs in the company. In the end, the costs for products through the supply chain for the end consumer also will increase. Lip seal rings PTFE / FKM for rotatory applications in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,001116 t/a. About emissions no information is available. b. Using the part together with a high gliding functionality and a high chemical resistance (dry or oiled air, CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) there is no friction, resulting in no micro particles that can enter the environment. Lip seal ring are used in lower speed rotary application to prevent an exchange of fluids and protection of internal parts in the rotary assembly. As Fluoropolymers such as PTFE have long chain "large molecules", recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If PTFE and FKM will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and physical properties (temperature range from +10 °C to+ 70 °C; Circumferential speed up to 2 m/s). Alternatives like single NBR or HNBR elastomer-based seals have lower temperature limits and chemical resistances. With higher circumferential speeds, the frictional heat is rising sharply and causes a shorter lifetime for the lip seal. Also, lower gliding properties reduce the efficiency of the machine and the machines' safety, resulting in rising energy consumption. The alternative materials will have to fulfill the same technical and chemical requirements during the whole service live of the lip seals. Spare parts for existing turning / milling machines will not be available anymore when the prohibition comes into place. Available alternatives will have a shorter lifetime. e. Searching for and testing of alternatives together with our suppliers will take five years or longer. For the chemical resistance large in-depth studies are necessary. f. A technically and economically feasible substitute is not available. g. Using alternative materials like thermoplastics leads to higher energy consumption due to higher friction and to more frequent replacements meaning higher service costs for our customers. A lowered service life leads to higher service costs, and to higher production costs for our customers. With higher production costs, more frequent service intervals and lower technical specifications, our customers lose confidence in our products. This means a drop in orders and a reduction in jobs in the company. In the end, the costs for products through the supply chain for the end consumer also will increase. Preloaded O-Ring seals based with PTFE or FKM wipers in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,00005 t/a. About emissions no information is available. b. Using the part combined with a PTFE or FKM wiper together with a high gliding functionality and a high chemical resistance (dry or oiled air, CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) there is no friction, resulting in no micro particles that can enter the environment. ring. As Fluoropolymers such as PTFE and FKM have long chain "large molecules", recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If PTFE and FKM will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and physical properties (temperature range from -10 °C to 50 °C; speed up to 1 m/s, pressure less). Alternatives like NBR or HNBR elastomer-based seals have lower chemical and physical resistances. The generated chips in the working area of a turning / milling spindle stress the material a lot. Due to the lower physical resistance replacements are more frequently necessary leading to higher material consumption and service costs. Especially the chemical resistance against coolants leads to a shorter lifetime of the wiper seals. While the temperature limitation of NBR or UHMW-PE is in the range of the wiper applications, these materials cause higher friction with higher speeds. Lower gliding properties reduce the efficiency of the machine and the machines' safety, resulting in rising energy consumption. The alternative materials will have to fulfill the same technical and chemical requirements during the whole service live of the O-ring wipers. Spare parts for existing turning / milling machines will not be available anymore when the prohibition comes into place. Available alternatives will have a shorter lifetime. e. Searching for and testing of alternatives together with our suppliers will take five years or longer. For the chemical resistance large in-depth studies are necessary. For alternative materials, the friction values must be checked. f. A technically and economically feasible substitute is not available. g. Using alternative materials like thermoplastics leads to higher energy consumption due to higher friction and to more frequent replacements meaning higher service costs for our customers. A lowered service life leads to higher service costs, and to higher production costs for our customers. With higher production costs, more frequent service intervals and lower technical specifications, our customers lose confidence in our products. This means a drop in orders and a reduction in jobs in the company. In the end, the costs for products through the supply chain for the end consumer also will increase. PTFE or FKM form wipers in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,496889 t/a. About emissions no information is available. b. Using the PTFE or FKM wiper together with a high gliding functionality, a high chemical resistance, and a long product life (dry or oiled air, CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) there is no friction, resulting in no micro particles that can enter the environment. PTFE / FKM wipers are used to clean up the painted or blank sheet-metal in the working area of the turning / milling machine from chips, coolant, and lubricants without damaging the surface of the sheets. As those, they have an important role in the working area of a turning / milling machine. As Fluoropolymers such as PTFE and FKM have long chain "large molecules", recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If PTFE and FKM will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and physical properties (temperature range from 10 °C to 50 °C; speed up to 40 m/min, pressure less). Alternatives like NBR or HNBR elastomer-based seals have lower chemical and physical resistances. The generated chips in the working area of a turning / milling spindle stress the material a lot. Due to the lower physical resistance replacements are more frequently necessary leading to higher material consumption and service costs. Especially the chemical resistance against coolants leads to a shorter lifetime of the wiper seals made of NBR. Without PTFE or FKM wipers, the universal resistance against a large range of coolants, from mineral oil based coolants up to synthetic coolants (based on polyolefins, alkylbenzenes, polyglycols, Carboxylic acid esters or polyol esters) cannot be covered. While the temperature limitation of NBR is in the range of the wiper applications, these materials cause higher friction with higher speeds. Lower gliding properties reduce the efficiency of the machine and the machines' safety, resulting in rising energy consumption. The alternative materials will have to fulfill the same technical and chemical requirements during the whole service live of the wipers. Spare parts for existing turning / milling machines will not be available anymore when the prohibition comes into place. Available alternatives will have a shorter lifetime. e. Searching for and testing of alternatives together with our suppliers will take five years or longer. For the chemical resistance large in-depth studies are necessary. For alternative materials, the friction values must be checked. f. A technically and economically feasible substitute is not available. g. Using alternative materials like thermoplastics leads to higher energy consumption due to higher friction and to more frequent replacements meaning higher service costs for our customers. A lowered service life leads to higher service costs, and to higher production costs for our customers. With higher production costs, more frequent service intervals and lower specifications, our customers lose confidence in our products. This means a drop in orders and a reduction in jobs in the company. In the end, the costs for products through the supply chain for the end consumer also will increase. PTFE gliding sheet cover in turning / milling machines: a. Depending on the amount of sold machines /a, and on the information out of the ERP System of our company, the tonnage of according to this application is 0,00574 t/a. About emissions no information is available. b. While in use, there is no friction of micro particles into the environment in the use of the PTFE with a high gliding functionality, a high of chemical resistance (CGLP lubricating oil, HLP 32/46 oil, grease, mineral oil-based coolants, synthetic coolants) and a long product life. PTFE gliding sheets are used to cover cast iron areas in slides to prevent reaming of electric cables and hydraulic hoses on the casting skin. Additionally, PTFE gliding sheets can be rolled to mount and disassemble them easily into the slide structure. Fast and easy disassembly is necessary to get access into the internal slide structure. The very low friction helps for longer part life of the cables and hoses. As Fluoropolymers such as PTFE generally have long chain "large molecules", their recycling at the end of their life cycle will be organized by incinerating. c. Number of companies in the sector: 1.500 companies in Europe d. If PTFE will be prohibited, like suggested in the restriction proposal, alternative products won't have similar technical and mounting properties, as a core component of the turning machine is affected. Alternatives made of high-grade steel don’t have the flexibility of the PTFE sheet foil for mounting and disassembling. Also, high-grade steel sheets costs are five times as high as the PTFE version. e. There are no technically valuable alternatives. f. A technically and economically feasible substitute actually is not available. g. Missing alternatives lead to very high service exchange rates for the hoses after the prohibition. With higher costs and lower technical values, our customers decline confidence in our products. This means a drop of orders and a reduction of jobs in the company. |

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| 8270 | Date:  2023/09/21 16:01  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  MTU Maintenance Berlin-Brandenburg GmbH  Org. country:  Germany  Attachment:    <redacted> | General Comments:  - |
| Answer to specific info request 1:  see attachment |
| Answer to specific info request 2:  see attachment |
| Answer to specific info request 3:  see attachment |
| Answer to specific info request 6:  see attachment |
| Answer to specific info request 8:  see attachment |

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| 8271 | Date:  2023/09/21 16:06  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  MTU Maintenance Berlin-Brandenburg GmbH  Org. country:  Germany  Attachment: | General Comments:  - |
| Answer to specific info request 1:  See attachment |
| Answer to specific info request 2:  See attachment |
| Answer to specific info request 3:  See attachment |
| Answer to specific info request 6:  See attachment |
| Answer to specific info request 8:  See attachment |

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| 8272 | Date:  2023/09/21 16:09  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:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  We as a producer of gloves which are used in several applications see the impact of such a generalized restriction of use very critical. Due to the fact that the Viton-glove is without any alternative right now and there would be a long time required to develop a proper alternative is a certain fact, we would request for exemption for fluoro elastomers; the end user would be either strongly restricted in the safe realisation of their activities or exposed to hazard/risks without an exemption. |
| Answer to specific info request 1:  PPE - Personal protection equipment for chemical industry |
| Answer to specific info request 2:  Manufacture phase: all residues and subproducts are incinerated during manufacturing process Use phase: no considerable indications end-of-life phase: we recommend to the end user a proper incineration of the product due to our attached use instruction |
| Answer to specific info request 6:  Due to the excellent stability of the chemical structure of FKM-based elastomers, and the properties resulting from this fact, their use in the manufacture of protective gloves, so called Viton-Glove, against organic solvents and various chemical substances makes this material unique and fundamental for the protection of the individual carrying them. One of the greatest advantages of using this material is its universality, meaning that it can be used for the most diverse substances. Replacing this material with alternative materials for making gloves is therefore quite complex, since such development depends not only on the availability of alternatives, such as complex and expensive polymers, for such use, but also and especially on the potential of producing gloves using known processes and in the desired design, that can withstand chemical substances and will have the potential to protect the user against solvents and other potentially aggressive and harmful substances for the user. Due to the exceptional properties of the material for protecting individuals and its universal nature, the development of alternatives to FKM in this application is scarce and especially poorly reported in the literature, even in patents. Therefore, the development of alternatives for the use of FKM in protective gloves will not only require intensive work time, but also a great deal of investment. In a rough estimation we consider a timeline of 5-6 years and an investment of € 350,000.00 – 400,000.00. |
| Answer to specific info request 8:  Besides to our own banned business, which would be the effect of the restriction, our customers would have a certain topics: The Viton-Glove is an unique product for heavy chemical protection in laboratories all over the world. Category III gloves applies to all complex PPE intended to act against lethal hazards or serious and irreversible damage to health. For example, one customer uses this glove product in conjunction with high proctection suits in automotive and chemical industry, for bioscience, for emergency services. In case of a restriction, there will be an impact of jobs at our customers and for the safety of the end user industry as well. |

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| 8273 | Date:  2023/09/21 16:14  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Leica Biosystems Nussloch GmbH  Org. country:  Germany  Attachment:    <redacted>  Privacy statement:  Quantities produced and sold, production secrets and processes and market shares are qualified as business secrets according to “Guidance on the preparation of public versions of Commission Decisions adopted under the Merger Regulation”. From the confidential information conclusions can be drawn about the company’s size, production volume, market share. In addition, according to Article 4(2) of Regulation (EC) No 1049/2001 our commercial interests, including intellectual property with regard to R&D effort have to be protected. | General Comments:  We are grateful to the ECHA for granting Leica Biosystems the opportunity to participate in the discussion on the Proposed Restriction on PFAS. For over 145 years, Leica Biosystems has been a global leader in the development of microtomy that is of extraordinary value for the examination of human and animal tissues with regard to basic sciences and cancer diagnostics. The company is a worldwide frontrunner in workflow solutions and automation, integrating every stage of the workflow from biopsy to clinical diagnosis. The Restriction Proposal concerning PFAS import, manufacturing, and usage directly affects the company because the PFAS polytetrafluoroethylene (PTFE) is a key component of the technique that ensures high quality histopathological cancer diagnostic. In fact, high-end quality blades coated with PTFE are needed for the preparation of thin and reproducible tissue slices. PTFE-based coating is exceptionally thin and exerts a negligible impact on the blade's geometric parameters ensuring the superior quality of histopathological slides and, consequently, improving the accuracy of diagnostics. In addition, PTFE-based coating possesses highly favourable tribological properties, preventing alteration of histopathological slides compared to usage of an uncoated blade and exhibits high hydrophobicity, providing resistance to soiling that could potentially cause damage of histopathological samples during the multiple sliding. The coating product used by Leica Biosystems (hereinafter referred to as CBMC) is a non-stick colourless coating (mixture) manufactured in the EU containing PTFE as main component. It has been intentionally designed for professional use as a specific coating for disposable blades of microtomes and cryostats used in research and clinical histopathological diagnostics. By using Leica Biosystems’ microtome blades high-quality slides of 0.5 μm up to 100 μm thickness from hard, soft, or frozen specimen can be prepared. Coating of the blades reduces the friction during sectioning that results in high quality sections consequently enhancing the quality of cancer diagnosis. Annually, Leica Biosystems sells more than one million single blades in the EU, with each blade providing in average 15 slides, resulting in more than 15 million slides. However, for this huge number of slides, Leica Biosystems purchases only less than 20 kg PTFE per year, resulting in less than 20 mg PTFE that is needed for coating of 1 blade and, theoretically, in less than 1.3 mg PTFE needed per slide. Each single slide of high quality can improve clinical diagnosis associated with accurate and timely disease detection and appropriate cancer therapy. This results in cost savings, improved patient outcomes, reduced healthcare expenses, and other economic indicators related to the diagnostic process. Healthcare effects are highly important for the socio-economic risk-benefit balance and taken into consideration in the Restriction Proposal, which provides specific derogation timeframes for certain PFAS specific uses. Currently, restriction option 2 (RO2) outlines a 13.5-year derogation for PFAS used for diagnostic laboratory testing (ECHA 2023a), and fluoropolymers (FPs) for certain medical usages. Additionally, further consideration is proposed for FP for coating applications for “medical devices other than metered dose inhalers”. Therefore, justification of derogation of 13.5 years for the use of the FP PTFE as a constituent of CBMC, blade coating for microtomes and cryostats, medical device for diagnostic (histopathological) laboratory testing is substantiated, but not sufficient. We expect more precise consideration on the specific usage of PTFE as a basic constituent of coating for microtomes and cryostats blades for histopathological cancer examination. This should be based on a thorough assessment of all risks associated with the final product (blades) quality alteration. 1.1 Scope or Restriction Option analysis PFAS represent the largest group of chemicals suggested for nearly complete ban due to the restriction proposed (ECHA 2023a). Obviously, such a group should not be considered as homogeneous for regulatory measures. It is recognized that PFAS could be subdivided in several ways (ECHA 2023a). Following OECD guideline (OECD 2021), all PFAS are categorized into two main groups based on their degradability. Additional methods of differentiation include factors such as carbon chain length and distinguish between non-polymeric and polymeric structures (Henry et al. 2018). Although FPs match the PFAS structural definition, they differ in their physical, chemical, environmental, and toxicological properties when compared with other PFAS. Accordingly, FPs such as PTFE should be considered as a distinct and separate group within PFAS concerning hazard assessment and regulatory purposes (FPG 2023; Henry et al. 2018; Korzeniowski et al. 2023). Among PFAS, PTFE holds a unique position due to its exceptional chemical stability. The polymer remains chemically inert under ambient conditions and can withstand temperatures up to 300°C. The chemical stability raises concerns about the persistence of PTFE. However, FPs only meets the persistence criterion and not the bioaccumulative, toxic, and mobile criteria (Améduri and Hori 2023). FPs (especially PTFE) have been extensively tested to satisfy US, Japanese and EU food contact and global medical device regulations, e.g., US Food and Drug Administration, China Food and Drug Administration, Korea Ministry of Food and Drug Safety, Japan Pharmaceutical and Medical Device Agency, including ISO 10993 biocompatibility testing and preclinical animal testing, and - as a polymer - also has been exempted from REACH legislation. Moreover, the restriction of FPs under REACH regulations may hamper the EU strategic sustainability as FPs are used in critical applications that help deliver strategic EU and UN climate objectives and are an enabler of the European Green Deal, the Chips Act, Hydrogen Strategy, and Sustainable and Smart Mobility Strategy. The proposed restriction creates general uncertainty that would undermine investment decisions and innovation in these and other important EU ambitions (FPG 2023). Thus, there is evidently a rationale to re-consider the inclusion of PTFE into the scope of ECHA Restriction Proposal on PFAS (ECHA 2023a) in general. 1.2 Hazard or exposure Hazard of PTFE It is recognized, that polymers, in general, are of less concern compared to monomers (ECHA 2023b). Potential risks of polymers to human health are still under estimation. Only a few studies with toxicological information are available for this diverse group of oligomeric and polymeric PFASs. The structures of side-chain fluorinated polymers as well as perfluoropolyethers are different from that of fluoropolymers. Little to no data is available on the toxicity of these two groups of polymeric PFASs (ECHA 2023a). Henry et al. (2018) demonstrated based on toxicity data, human clinical data, and the physicochemical properties of PTFE warrant its classification as a polymer of low concern. Fluoropolymers are high molecular weight, have narrow molecular weight distribution, and have negligible oligomer content and organic and inorganic leachables. Data show that fluoropolymers have thermal, chemical, photochemical, hydrolytic, and biological stability. Toxicology studies on PTFE demonstrate the absence of acute or subchronic systemic toxicity, irritation, sensitization, local toxicity on implantation, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombogenicity. Recently, Lee et al. (2022) assessed the toxicity of orally administered PTFE in doses ranging up to 2000 mg/kg in the form of microplastic (diameter of 5 µm and 10–50 µm). No adverse effects were observed in either single-dose (OECD 423) or four-week (OECD 407) toxicity studies conducted in ICR mice; notably, PTFE did not become systemically available. Exposure to PTFE associated with the manufacture/use of coated blades PTFE in CBMC, as coating for blades for microtome technic is purchased and used in a quantity between 1 and 20 kg per year. The process of coating is carried out as industrial use by Leica Biosystem. The usage of PTFE during the manufacturing and final product use does not pose a hazard, as both processes are controlled and do not involve exposure of PTFE to high temperatures. 1.3 Environmental emissions Due to the low annual amounts of PTFE used by Leica Biosystems, the controlled manufacturing process and professional use of CBMC, environmental emissions of PTFE during manufacturing and use of blades for microtomes and cryostats are negligible at all stages. Emissions can be managed accordingly to current protocols adopted for this field. The results of recently published studies on the waste combustion of PTFE have demonstrated that municipal incineration of the polymer utilizing best available technologies should be regarded as an acceptable approach to PTFE-containing waste treatment (Aleksandrov et al. 2019). There is no statistically significant evidence that PFAS (including wide range such as perfluoro-carboxylic acids and trifluoroacetic acid) were formed in flue gas during the industrial incineration of PTFE. 1.4 Baseline The estimated average annual emissions of polymeric PFAS used for medical devices total up to 76 tonnes per year (ECHA 2023a, p. 41). Among these, PTFE constitutes approximately 37% of all PFAS employed within the medical device industry (ECHA 2023c, p. 87), resulting in 28.12 tonnes PTFE per year. The proportion of PTFE used by Leica Biosystems (between 1-20 kg per year) in the coating of blades for microtomes and cryostats is below 0.07% of the current PTFE baseline adopted for medical devices. In conclusion, all life stages of PTFE-containing coating CBMC are well controlled as the material is designated only for industrial and professional use. This can effectively prevent/minimise risk of emissions of PTFE. 1.5 Information on alternatives According to ECHA (2023a, p.100), there is sufficiently strong evidence that technically and economically feasible alternatives are generally not available for diagnostic laboratory testing indicating a low substitution potential. The substitution of PTFE in the coating of blades for microtomes and cryostats necessitates more than just replacing PTFE with a non-PFAS alternative. It also requires the development of specific material, that ensures preparation of a comparably high quality of histopathological slides used for cancer diagnostics. Additionally, as it is mentioned in the Annex E (ECHA, 2023d, p. 321), “there is a concern that the potential alternatives would also be persistent in the environment due to their necessary characteristics”. Within the scope of Leica Biosystems´ own research no alternative material could be identified on the market which fulfils the required properties and is cost-effective. 1.6 Information on benefits With the introduction of disposable microtome blades 50 years ago, the PTFE-coated disposable microtome blade became the gold standard in research and clinical microtomy applications. CBMC is a crucial element of histopathologic technique, which ensures improved clinical histopathological cancer diagnostics with the consequence of better patient outcomes; reduced healthcare costs; enhanced research opportunities; and broader societal advantages for patients through effective disease management and resource allocation. The use of PTFE as the main functional component for coating blades of microtomes and cryostats requires only a small amount of the FP, providing “state-of-the-art” histopathological technique. A ban of PTFE on microtome blades without a reliable alternative would inevitably impair research workflow and disrupt histopathological cancer diagnostics. No socio-economic benefit is expected from restricting the use of PFAS PTFE for coating for medical devices, such as blades for microtomes and cryostats produced by Leica Biosystems. 1.7 Other socio-economic analysis (SEA) issues If the EC chooses to restrict Leica Biosystems to Restriction Option 1 (RO1) with regard to the use of PTFE as coating substance for microtomes and cryostats blades for histopathological clinical diagnostic the ban would impact the immediate business as the production would be stopped within 18 months and clearance of current stock. With no existing alternative available, cancer diagnostics would be affected resulting in false-diagnosis or even non-diagnosis due to the resulting bad quality sectioning from uncoated blades. Hence, a ban of PFASs would have substantial impacts on the feasibility of diagnostic laboratory testing, which in turn would have severe implications on public health resulting in high socioeconomic costs. Although the restriction option proposed by ECHA is RO2 with a transition period of 13.5 years, this time would not be sufficient to find or develop a suitable alternative and to establish the quality of all subsequent diagnosis measures. Therefore, the consequences would be similar to those of RO1. 1.8 Request for exemption Given the distinctive unique properties of PTFE, we respectfully request exemption for the utilization of PTFE in the coating of blades for microtomes and cryostats from the scope of Restriction Proposal (ECHA 2023a). This request is based on the extremely high socio-economic value of PTFE used in minimal quantities as a crucial element, providing high quality of histopathological cancer diagnostics and research in this field.  List of references Aleksandrov K, Gehrmann HJ, Hauser M, et al. (2019) Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per-and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Chemosphere 226:898-906 Améduri B and Hori H (2023) Recycling and the end of life assessment of fluoropolymers: recent developments, challenges and future trends. Chem Soc Rev 52:4208-47 ECHA (2023a) Annex XV Restriction Report: Proposal of a Restriction of per- and polyfluoroalkyl substances (PFAS). Version: 2, 22.03.2023, pp1-224 ECHA (2023b) Guidance for monomers and polymers. February 2023, Version: 3.0, pp1-26 ECHA (2023c) Annex (A) to the Annex XV Restriction Report: Proposal of a Restriction of per- and polyfluoroalkyl substances (PFAS). Version: 2, 22.03.2023, pp1-299 ECHA (2023d) Annex (E) to the Annex XV Restriction Report: Proposal of a Restriction of per- and polyfluoroalkyl substances (PFAS). Version: 2, 22.03.2023, pp1-556 FPG (2023) The restriction of fluoropolymers under REACH will hamper key EU strategic sustainability ambitions. Fluoropolymers Product Group, 2023, pp 1-2 Henry BJ, Carlin JP, Hammerschmidt JA, et al. (2018). A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag 14: 316-34 Korzeniowski SH, Buck RC, Newkold RM, et al. (2023) A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag 19:326-54 Lee S, Kang KK, Sung SE (2022) In vivo toxicity and pharmacokinetics of polytetra-fluoroethylene microplastics in ICR Mice. Polymers 14: 2220 OECD (2021) Reconciling terminology of the universe of per-and polyfluoroalkyl substances: recommendations and practical guidance. Ser Risk Manag, 61, 1-34 |
| Answer to specific info request 1:  The use of the PTFE-containing mixture CBMC for coating of blades for microtomes and cryostats for histopathological clinical diagnostic is relevant for the following use sector: Medical devices; with the respective sub-uses: - Diagnostic laboratory testing; - Other coating applications (Coating for medical devices other than Metered Dose Inhaler [the use is indicated in the Restriction Proposal as being "under reconsideration”]). |
| Answer to specific info request 2:  According to the information available in ECHA Restriction report, Annex E it is assumed that in case of polymeric PFAS 1% of PFAS is emitted during use (ECHA 2023d, p. 316). Consequently, the anticipated annual emissions of PTFE, when used as a component of CBMC at Leica Biosystems, is expected to average below 0.2 kg per year. At the stage of manufacturing, Leica Biosystems provide the following risk management measures to prevent emission: - closed coating chamber; - no wastewater is produced; - collection of a non-compliant blades/production residues and following incineration during melting down with ferrous scrap. Although the use phase is out of manufacturer control, in practice, the professional use of the coating allows to control the substance emissions over its use and disposal. The primary packaging of blades is designed specifically to protect individual articles from any mechanical damage before installation onto microtome, therefore emissions of polymer are prevented. After use the coated blades cannot be recycled but must be collected and eventually incinerated as hazardous waste as blades are handled as sharps according to waste regulations. |
| Answer to specific info request 3:  The use phase and the end-of life phase can be distinguished in 2 categories. 1 (mainly): Contact with infectious tissue (mainly when used on cryostats in clinical environment) 2 (in rare cases): Sectioning without contact of infectious material (Mainly paraffin sectioning on microtome and research applications) During the use phase and the preparation of slides following material gets into contact with the PFTE containing cutting edge: sample block, waste sections and sectioned sample for diagnosis. Such tissue is commonly treated as infectious material which is commonly incinerated. Blades are handled as sharps according to waste regulations. Waste management of above material including the used microtome blade will be handled as follows: 1 (mainly): contact with infectious samples: all material needs to be collected and disposed as infectious material through special waste incineration to avoid releasing infectious agents 2 (in rare cases): normal waste: all materials are considered to be residual waste as long as sharp material (like microtome blades) are safely enclosed to avoid cutting. Our instruction for use for microtome blades clearly states that non infections used blades need to be inserted into our safe waste container included in our dispenser box. Further waste management of such residual waste underly regulations of individual countries, e.g., in Germany this residual waste is most often incinerated. Used blades which are not subject to incineration is considered very small, it is assumed to be 3%. Aleksandrov et al. (2019) reported that municipal incineration of PTFE using the best available technologies should be considered an acceptable waste treatment method. It was shown that PTFE can be almost fully transformed into fluorine (F) (as hydrofluoric acid (HF)). To study the possible generation of low molecular weight per- and polyfluorinated alkyl substances (PFAS), PTFE combustion under typical waste incineration conditions was investigated. No evidence of PFAS formation (including wide range such as perfluoro-carboxylic acids and trifluoroacetic acid) during the incineration of PTFE was observed. As stated above it is assumed that approximately 1% of the maximum 20 kg used by Leica Biosystems per year are released into the environment during use resulting in less than 0.2 kg per year. In addition, it is assumed that 97% of all blades are properly disposed of and are subject to incineration. Consequently, the anticipated annual emissions of PTFE, in the end-of-life phase at Leica Biosystems, is expected to average below 0.6 kg per year. |
| Answer to specific info request 5:  The annual quantity of PTFE used for CBMC production is between 1-20 kg, enabling the manufacturing of more than 1 million single blades marketed in the EU. The resulting emissions during manufacturing and use have not been assessed yet, but they are expected to be negligible. This suggestion is based on the small quantity of the substance used, exclusively industrial use of the substance-containing product and efficient degradation of PTFE during waste incineration, which collectively prevents any significant emissions. |
| Answer to specific info request 7:  According to ECHA Proposal of a Restriction of per- and polyfluoroalkyl substances (ECHA 2023a, p.100), there is sufficiently strong evidence that technically and economically feasible alternatives for the use in diagnostic laboratory testing are not generally available indicating a low potential for substitution. Given the distinctive unique properties of PTFE, we respectfully request exemption for the utilization of PTFE in the coating of blades for microtomes and cryostats from the scope of Restriction Proposal (ECHA 2023a). This request is based on the extremely high socio-economic value of PTFE used in minimal quantities as a crucial element, providing high quality of histopathological cancer diagnostics and research in this field With regard to questions a-g: a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use. PTFE is the main component of the coating specifically designed for blades used in histopathological clinical diagnostic of cancer. The annual tonnage of PTFE for this use is minimal, amounting to maximum 20 kg. The quantity enables the production of more than 1 million blades sold within the EU per year. The resulting emissions have not been assessed yet, but they are expected to be negligible even in a worst-case scenario. This suggestion is based on the small quantity of the substance used, exclusively professional use of the substance-containing product and efficient degradation of PTFE during waste incineration, which significantly reduces potential emissions. b. The key functionalities provided by PFAS for the relevant use. PTFE containing coating for the microtome blades introduced 50 years ago became a gold standard in clinical and research microtomy applications. These blades are used in histology laboratories around the world focusing on the biopsy and sectioning of human tissues being crucial in cancer diagnostics. PTFE has very specific intrinsic advantages as it is a non-wetting, anti-stick, hydrophobic material. This property helps the blade edge to glide over the tissue during sectioning, provides better ribboning of the sections during application, improves the quality of individual sections. All these properties improve cancer diagnosis and reproducibility of the results. Additionally, PTFE prevents adherence of bio-hazardous tissue to the blade edge providing better control of bio-hazardous materials. The PTFE-based coating is: - exceptionally thin and exerts a negligible impact on the blade's geometric parameters ensuring the superior quality of histopathological slides and, consequently, enhancing the success of diagnostics; - possesses highly favourable tribological properties, preventing alteration of histopathological slides compared to usage of an uncoated blade; - exhibits high hydrophobicity, providing resistance to soiling that could potentially cause damage of histopathological samples during the multiple sliding; additionally, resistance to the soiling provides better control of bio-hazard associated with histopathological samples; Consequently, the utilization of the coating not only extends the blade's lifecycle compared to an uncoated blade, but drastically enhances the precision and reliability of the diagnosis. c. The number of companies in the sector estimated to be affected by the restriction. See Confidential Attachment 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. There are no alternative-based coatings available for this specific use on the EU market. For additional information see confidential attachment. 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. As a world leader in the histopathological diagnostic equipment sector with nearly 150 years of experience, Leica Biosystems is dedicated to researching and developing alternatives to provide both enhanced clinical cancer diagnostics and improved tools for scientific research in the field of healthcare and medical science. Currently, PTFE-containing coating remains the gold standard and no suitable alternative is found, and there is still no sign that alternative coating will be obtained. Leica Biosystems planned to continue with further R&D projects. R&D of PTFE-free coating is now at the stage of planning of the initial stage. For the moment is not feasible to assess 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. The main problem with finding suitable alternatives for PFAS lies in their useful properties like non-wetting, hydrophobic and low friction coefficient. Any potential material should exhibit the similar properties and quality of sections besides being cost-effective. From scientific point of view there are currently no material which can exhibit similar properties. Bio-compatibility is another point to be considered for research. The PTFE health and environment safety profile has been thoroughly evaluated and no concerns regarding its use have arisen up until the publication of the ECHA Restriction Report. Currently no alternative with comparable functionality to PTFE for specific use as blade coating is known. Furthermore, there is no assurance that any potential alternatives would possess a superior safety profile compared to PTFE. 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. Given the exceptionally high social value of CBMC due to its crucial role in public healthcare (clinical diagnostic of cancer) and the minimal annual tonnage of PTFE for this purpose, concerns about the safety of PTFE are counterbalanced by the substantial social benefits it provides. Only an alternative that provides at least comparable quality for clinical diagnostics can be considered as relevant and acceptable. PTFE as constituent of coating CBMC has extremely high social value being a key functional element of blades for a clinical histopathological diagnostic. A ban of PFASs would have substantial impacts on the feasibility of diagnostic laboratory testing, which in turn would have severe implications on public health resulting in high socioeconomic costs. In addition, the socio-economic impact of Leica Biosystems is an important factor to consider. A ban would impact the immediate business as the production would be stopped within 18 months. |

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| 8274 | Date:  2023/09/21 16:14  Content:  Hazard or exposure  Environmental emissions  Type:  BehalfOfAnOrganisation  Org. type:  Regional or local authority  Org. name:  Landratsamt Rastatt  Org. country:  Germany  Attachment: | General Comments:  Statement of the district of Rastatt on the planned PFAS restriction at European level   On January 13, 2023, the Netherlands, Germany, Denmark, Sweden and Norway took the first formal step towards a European restriction on PFAS by jointly submitting a restriction proposal to the European Chemicals Agency (ECHA). The proposal aims to restrict both the use and manufacture of PFAS in order to reduce the risks posed by these substances to humans and the environment. Adoption would result in the most comprehensive substance restriction in Europe to date. The proposed restriction is highly complex because there are more than 10,000 different types of PFAS used in a wide variety of products. ECHA published the PFAS restriction proposal on February 7, 2023. The six-month public consultation is currently underway and is expected to end in September 2023. A final decision is not expected before 2025.  The district of Rastatt as well as the districts of Baden-Baden and Mannheim have had painful experiences with the PFAS group of substances. Due to application of paper sludge mixed with compost on arable land, about 1,100 hectares of soil in Central Baden are classified as contaminated. In addition to this considerable surface contamination, the groundwater from Rastatt to Ottersweier is also contaminated with PFAS. In total, an affected area of 200 km² has been delineated. The people in the district of Rastatt have to live with this pollution and are affected by it in many ways.  Due to the persistence of the pollutants, this problem will challenge the district of Rastatt and its population for decades. A comprehensive remediation is not possible and not financially feasible due to the dimension of the damage. Since 2013, an amount in the mid-double-digit millions has already been spent by the state, the district, the municipalities, the water suppliers and agriculture to protect the population. An ongoing financial burden will remain. These costs are essentially carried by the general public, but not by the producers and distributors of PFAS.  There is opposition to the planned PFAS restriction from industry associations. The Conference of Economics Ministers has endorsed these concerns (see attachment 1) , while the Conference of Environmental Ministers (see attachment 2), along with the Conference of Agriculture and Consumer Protection Ministers, has spoken out in favor of rapid implementation of the PFAS restriction.  From a scientific point of view, it is recognized that even PFAS with low acute toxicity pose a health risk in case of prolonged (chronic) exposure. The Special Report of the German Advisory Council on the Environment states that PFAS have already spread worldwide in the environment and accumulated in organisms including humans.  It is clear that mass production for countless consumer products for which substitutes already exist or for which there are no significant disadvantages in eliminating PFAS (e.g. cosmetics, food packaging or disposable cups) must be stopped as quickly as possible. The restriction proposal currently under consideration serves to protect humans and also grants industry long transition periods. In addition, substitutions with other substances are supported by research projects. Regular validation is planned to allow essential applications for which there are no substitute substances to continue, through derogations. In this way, industrial concerns are adequately taken into account in consideration of health and environmental protection.  The environmental administration of the district of Rastatt is committed to the EU restriction proposal in view of the dimension of the damage and the burden on the general public, the living conditions soil and water and the population in the district of Rastatt. It expressly welcomes the efforts of the Federal Republic of Germany to obtain a rapid and far-reaching PFAS ban in accordance with the restriction proposal at the European level for the protection of people and the environment.  An statement with the same content by the Committee for Environment, Construction and Planning of the District of Rastatt is expected to be adopted on 26.9.2023.  Attachments: Attachment 1: Resolution of the Conference of Ministers of Economics on June 21/22, 2023 at Schloss Hohenkammer Attachment 2: 100th Conference of Environment Ministers on May 12, 2023 in Königswinter |

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| 8275 | Date:  2023/09/21 16:14  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:  Industry or trade association  Org. name:  ASSOCIATION OF METALTECHNOLOGY INDUSTRIES  Org. country:  Austria  Attachment: | General Comments:  Position of the Austrian Metalworking Industry  "For a risk-based approach to PFAS - no general ban".  PFAS are used in a wide range of industrial applications, including critical applications, and are an essential part of many technologies and industrial processes that are central to the implementation of the Green Deal, but also to other Union priority objectives such as human health and safety. The proposed REACH restriction undermines investment decisions and innovation to achieve these goals.  For example, fluoropolymers were identified as strategic materials in a recent report published by the European Commission's Joint Research Centre (JRC), "Supply Chain Analysis and Material Demand Forecast in Strategic Technologies and Sectors in the EU - A Foresight Study". They are an integral part of technologies such as fuel cells, in power generation (including photovoltaics, solar thermal, wind power, energy storage systems), electronics, semiconductors and various industrial applications. They have an almost universal resistance to aggressive media, withstand high mechanical and thermal loads, have unrivalled dielectric properties, have very good flexibility and, unlike any other material, are permanently low in emissions and extremely durable. Meeting the combination of these very demanding requirements makes fluoropolymers indispensable. There are no materials on the market, either known or under development, that can meet the combination of high thermal resistance (~200°C), high flexibility, high mechanical resistance and high chemical resistance. |
| Answer to specific info request 1:  Please see attached document |
| Answer to specific info request 5:  Please see attached document |
| Answer to specific info request 6:  Please see attached document |
| Answer to specific info request 8:  Please see attached document |

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| 8276 | Date:  2023/09/21 16:17  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  The scope of the products described in this document concerns the components that are required to form a radio frequency coaxial connection for professional (i.e. non-household) uses. Examples of such components are: connectors and adapters, terminators, suppressors, RF switches, seals or cables. The components are used in addition or combination with coaxial connectors in the same markets and applications. Although RF coaxial connections may differ in their specific function, the general findings of this response and the lack of alternatives to polymeric PFAS-materials apply to all RF coaxial connections in the same way. They are based on basic physical properties, e.g. permittivity, thermal and chemical stability of specific fluoropolymers.  As it will be further justified in this document, the RF Coaxial Connectors Manufacturers Group request the following two derogations:  i) Polymeric PFAS in components required to form a radio frequency coaxial connection for non-household uses, as for example coaxial connectors, adapters, terminators, suppressors, switches, seals and cables until 13,5 years after EiF. ii) Spare parts for i) until 10 years after expiry of i).  The group members do not have enough knowledge about the use of polymeric PFAS in household coaxial connections and excluded these uses from the derogation request. This cannot be understood in a way that the group members would have any evidence that polymeric PFAS are or are not required in such connections.  Justification of the Derogation Request:  ● Currently no material with the required basic physical properties exists that could act as a drop-in substitute for currently used polymeric PFAS materials. ● Development of alternative materials is an on-going process and only partially influenced by the manufacturers of coaxial parts as they are in the role of downstream users. ● The currently available alternative materials would require a re-design of the components of the coaxial connection, which will cause a cascade reaction: coaxial components using non-PFAS materials will get bigger than the ones with polymeric PFAS-materials. Accordingly, also the subsystems that are based on the coaxial connection will have to be re-designed and will get bigger. In consequence, also the final system (e.g. the mobile radio antenna) will need re-design and the intended miniaturization to safe material and space will not apply anymore. ● Substitution of the safety and function relevant polymeric PFAS parts in a coaxial connection is a complex and time-consuming process that is described in annex 3, once the availability of substitutes developed by the chemical industry will be effective. The estimated timeline of this step by step process is more than 13,5 years and involves suppliers, in-house resources, customers, and standardization committees. Please find details in annex 3 ● Exhaustive engineering and administrative work will be required (minimum 20000 drawings for each company to update) that will bind resources that would otherwise develop new products. ● Besides, after the expiry of the requested derogation, it will be ecologically and economically more feasible to repair or renew existing systems by using spare parts than to replace the whole system. The use of the exemption for spare parts will be applied less and less over the years. ● The coaxial connections, the derogation request refers to, are only installed and dismantled by professional users. The polymeric PFAS materials in these connections cannot be routinely touched (only seldom or accidently touching during production or installation is possible). Scrap of polymeric PFAS material generated during the production of the components of the coaxial connections are collected and given back to the material producer for recycling or thermal recovery. Accordingly, from the component manufacturer´s point of view´s cradle (i.e. the polymeric PFAS granules or semis) to the grave (i.e. dismantling of the components), no uncontrolled release of polymeric PFAS material is possible. We do not have enough evidence to fully quantify if at all relevant release of polymeric PFAS material is possible during the whole life cycle from production of polymeric PFAS granules/semis to the recycling or thermal recovery of the dismantled components. If such a release happens, the group members estimate it as extremely small.  The group members are highly concerned, as:  ● A ban on polymeric PFAS in professional coaxial connections without derogation would have severe negative impacts on basic societal requirements. Improvements intended by major EU legislation like the EU Green Deal or the EU Chips Act would be hindered or even impossible. ● The following sectors which rely on coaxial connections are directly impacted:  5G maintenance and deployment, compromising the future deployment of 5G+ and 6G;  Critical communications: radio communication of police, armed forces, emergency services (e.g. TETRA);  Internet access and downloading, cell phone access, video streaming, etc.;  Space, aeronautics, civil and defense programs: critical signals for take-off, landing, flight and therefore the absence of aircraft or satellites;  Measurement equipment, and therefore on R&D and qualifications;  Smart networks and chip testing equipment: direct negative impact on the EU Green Deal and the EU Chips Act;  MedTech;  Quantum computing;  Autonomous driving, train control and connectivity.  ● In a time of less stable supply chains and lack of professional staff, there are no resources left to lower these impacts. ● A change in the material would mean that the components could no longer be manufactured in accordance with international standards (IEC and MIL). This would mean that worldwide compatibility of the systems would no longer be possible. ● The competitiveness of the European manufacturers will be weakened against the rest of the world, as well as the one of all the downstream and upstream users. ● From a purely economic point of view, a ban of polymeric PFAS in professional coaxial connections can never be justified because it causes high additional costs for the manufacturers and even more for consumers and states due to enhancing the costs of products and services while no additional further function or other further benefit would result. ● From a purely ecological point of view, a ban of polymeric PFAS in professional coaxial connections without derogation is not justified as it would cause thousands of times more unnecessary waste from associated obsolete equipment for each amount of polymeric PFAS saved. ● As it is not known if during the production or waste treatment of components of professional coaxial connections polymeric PFAS are released at all and in which amount, it is not possible to estimate the health impacts or costs caused by this use. During the use phase, no release is possible. |

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| 8277 | Date:  2023/09/21 16:19  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  VDMA EA  Org. country:  Germany  Attachment: | General Comments:  Der Maschinen und Anlagenbau ist nicht aufgeführt als Sektor im Restriktionsvorschlag. Es werden Dichtringe, Kabel und Sensoren für die gesamte Branche der deutschen und europäischen Industrie und kritischen Infrastruktur produziert. Aus diesem Grunde erbitten wir eine Ausnahme von der Anwendung von PFAS bei der fehlenden Verwendung von FKM. |
| Answer to specific info request 6:  See attachement |

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| 8278 | Date:  2023/09/21 16:18  Content:  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |

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| 8279 | Date:  2023/09/21 16:25  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  International NGO  Org. name:  CHEM Trust  Org. country:  Germany  Attachment: | General Comments:  Please see CHEM Trust general comments and supporting evidence submitted as a non-confidential attachment |

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| 8280 | Date:  2023/09/21 16:24  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Associazione Produttori di Guarnizioni del Sebino  Org. country:  Italy  Attachment: | General Comments:  See attachment |
| Answer to specific info request 1:  See attachment |
| Answer to specific info request 2:  See attachment |
| Answer to specific info request 3:  See attachment |
| Answer to specific info request 4:  See attachment |
| Answer to specific info request 5:  See attachment |
| Answer to specific info request 6:  See attachment |
| Answer to specific info request 7:  See attachment |
| Answer to specific info request 8:  See attachment |

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| 8281 | Date:  2023/09/21 16:27  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Solvay - Specialty Polymers  Org. country:  Belgium  Attachment:    <redacted>  Privacy statement:  “Confidential treatment should be granted to the annexed documents on the ground of the protection of Solvay’s commercial interests, pursuant to Article 4(2), first indent of the PAD Regulation. The PAD Regulation does not define the concept of commercial interests, except in so far as it specifies that such interests may cover the intellectual property of a particular natural or legal person. The EU Courts nevertheless stress that information withheld under the exception relating to the protection of commercial interests is information which is not generally known to persons belonging to the circles dealing with the type of information in question, within the meaning of that provision. The Court held that it is in principle appropriate for an EU institution to rely on general presumptions applying to certain categories of documents, similar general considerations being likely to apply to requests for disclosure of documents of the same nature (Joined Cases C 39/05 P and C 52/05 P, Sweden and Turco v Council, EU:C:2008:374, paragraph 50). In this respect, the General Court has for example confirmed that information on company methods and expertise, specific prices, details of budgets and timetables involved, and elements of business strategies were covered by a general presumption that their disclosure would in principle undermine the protection of commercial interests of the company and that the EU institution therefore did not have to put forward any concrete evidence to justify the non-disclosure of each document, in its entirety (Case T-651/21, Hans-Wilhelm Saure v Commission, EU:T:2022:526, paragraphs 106 and 107). In this case, the documents submitted contain numerous business secrets and proprietary data of Solvay that are not available in the public domain. Specifically, the documents contains business secrets and proprietary data such as, inter alia, (i) the commercial strategy (including for the future) put in place by Solvay relating to PFAS, (ii) detailed data on Solvay’s PFAS portfolio (including on product names, their production process and production site, or their physicochemical properties), (iii) numerical data of Solvay (such as percentages or financial data) relating to PFAS, and (iv) the Best Available Technologies measures put in place by Solvay relating the minimization of PFAS emissions. This expertise and this know-how are not publicly available and their disclosure would cause significant harm to the competitive position of Solvay as it would undermine its commercial interests, including intellectual property. Indeed, knowledge of such information could allow third parties such as an applicant for public access to documents to discover the proprieties and composition of products manufactured and placed on the market by Solvay, as well as Solvay’s commercial strategy and interests, which could ultimately undermine the commercial interests of Solvay. Confidential treatment should consequently be granted to the attached document in application of the exception to disclosure contained in Article 4(2), first indent of the PAD Regulation.” | General Comments:  Solvay Specialty Polymers has prepared a confidential dossier about fluoropolymers (FPs) and perfluoropolyethers (PFPEs) which is divided into 4 chapters. Chapter 1 (containing a few amendments in comparison to the previously submitted version) contains information about Solvay’s general position on the EU PFAS restriction proposal and summarizes technical information on hazard, emissions, alternatives and socio-economic impacts which are detailed along chapters 2, 3 and 4, respectively. Chapter 2 provides information on hazard and environmental properties of Solvay’s product portfolio. Chapter 3 includes information on emissions along the life cycle, focusing on the production and end of life phases. Finally, Chapter 4 summarizes the market knowledge about alternatives and provides socio-economic information, including potential impacts of the restriction on Solvay.  Solvay Specialty Polymers believes that FPs and PFPEs manufactured without fluorosurfactants and that fulfil the criteria of Polymer of Low Concern (PLC) should be excluded from the scope of the proposal, or should be exempted by way of a time-unlimited derogation for all uses, as they do not present an unacceptable risk that needs to be addressed at the EU level by means of a REACH restriction, due to their recognised low hazard to human health and the environment. Additionally, PFPEs not meeting all PLC criteria should be derogated according to DUs requests, where they are solely applied in industrial uses, present low (eco)tox risk according to their conditions of use and have no technically (in terms of performance) and economically feasible alternatives. |
| Answer to specific info request 1:  “Solvay Specialty Polymers, as one of the largest global manufacturers of FPs and PFPEs, supplies products to several sectors, including: - Batteries - Hydrogen - Automotive - Aeronautics - Semiconductor - Industrial applications (such as lubricants and sealant use) - Oil & Gas (O&G) For more information, please see attached confidential document, specifically chapter 4 |
| Answer to specific info request 2:  As one of the main fluoropolymers (FPs) and perfluoropolyethers (PFPEs) producers, we share information on production, emissions and on-going projects on end of life. For more information, please see attached confidential document: “Chapter 3 - emissions” |
| Answer to specific info request 3:  As one of the main fluoropolymers (FPs) and perfluoropolyethers (PFPEs) producers, we share information on publicly available and Solvay proprietary studies. For more information, please see attached confidential document: “Chapter 3 - emissions” |
| Answer to specific info request 5:  For more information, please see attached confidential document: Chapter 3. |
| Answer to specific info request 6:  We mapped Solvay known applications and among them some missing uses have been identified. |
| Answer to specific info request 8:  Solvay Specialty Polymers shares its view on the (non-)availability of alternatives and the potential socio-economic impact of restriction proposal. For more information, please see attached confidential document: Chapter 4. |