**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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| 9047 | Date:  2023/09/24 16:30  Content:  Scope or restriction option analysis  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sansho shoji co. ltd  Org. country:  Japan | General Comments:  Sansho Shoji Co., Ltd. is a trading company in Japan. We appreciate the opportunity to submit comments about the proposed restriction. We handle PTFE membranes, and our main customers are EDLC manufacturers and alkaline ionized water apparatus manufacturers in Asia. The amount of PTFE we sell is about 0.5 tons per month, and it accounts for not small percentages of our whole sales. Our customers have tested several materials to find alternatives to PTFE membranes but proved that none of them are really useful. Besids, the PTFE membrane manufacturer, has no clue about the alternatives. Considering the current situation, we believe that 5 or 16 years is too short to develop alternatives for PTFE membranes. At this point, no other material than PTFE membrane can fulfill our customers' requirements, which means our customers' products would not work without PTFE membrane, and it would cause serious economic damage for us and our stakeholders. |
| Answer to specific info request 1:  food contact materials and medical devices, and electronics |

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| 9048 | Date:  2023/09/24 16:43  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  National NGO  Org. name:  <redacted>  Org. country:  Sweden  Company name confidential:  Yes | General Comments:  The Swedish Defence Industry Association (SOFF) represents 200 defense companies of various sizes. We've observed that the dossier submitters have not taken into account the utilization of aeronautic, space, security, and defense (collectively referred to as aerospace and defense) sectors. The proposed restriction option 2 (RO2) has been developed without considering the unique characteristics of our sector. The current proposed restriction would have severe consequences as it would halt aviation, space, and defense activities, including production, imports, and maintenance, just 18 months after its implementation. In our comments, we emphasize the necessity of incorporating the specific needs of our sector in the proposed restriction options by the dossier submitters. Aerospace and defense products encompass both civilian and military aeronautics (comprising various aircraft and associated ground equipment), a range of security and defense products (including naval vessels, armored vehicles, weapon systems, and munitions), and space equipment such as satellites, launchers, and communication systems. These products share the common requirement of operating under extreme conditions and adhering to stringent safety and reliability standards. Formal quality management systems, like AS9100, are in place to ensure compliance with these standards throughout the manufacturing, operation, and maintenance (Maintenance, Repair, and Overhaul or MRO) processes. Any changes to product design are subject to rigorous formal change management procedures. MRO activities must use parts and components manufactured according to the approved design. Regarding the use of PFAS chemicals in aerospace and defense products, we address this in our response to Q6. PFAS chemicals play an integral role in the production, operation, and MRO of these products. We provide 20 illustrative case studies, each outlining the application, the role of PFAS chemicals in performance, the availability of alternatives, and the impact of the proposed restriction on the application. Notably, fluoropolymers, used widely as seals, sealants, gaskets, lubricants, bearings, and more across these products, lack immediate drop-in alternatives due to stringent performance requirements. Substitution timelines depend on the identification, commercialization, and industrialization of new alternatives, which may take years. We emphasize that the scale of substitution required is unprecedented, affecting thousands of parts, components, systems, etc., essential for production, operation, and MRO across aerospace and defense products. The economic impact extends beyond manufacturing jobs, potentially leading to the cessation of civilian aircraft production in the EEA, outsourcing of scheduled maintenance, and dependence on aging fleets. Defense forces would face critical challenges, including an inability to maintain existing products, procure new ones, or replenish weapon stocks, jeopardizing Europe's sovereignty. Due to these reasons, we request that the dossier submitters modify their restriction proposal to explicitly consider our sector and its unique requirements. We ask them to take into account: • Formal quality management systems, particularly stringent certification processes (e.g., AS9100 and NATO standards). • The absence of suitable alternatives meeting safety and reliability standards. • The lengthy substitution process. • The extensive R&D activities needed. • The complexity of products manufactured from numerous parts via global supply chains. • Interdependencies across products. • The need for adequate derogation coverage. • The inadequacy of a 12-year derogation period. • The necessity of a review clause. • The prevalence of fluoropolymers in aerospace and defense products. • The reporting requirements and administrative burden. Specifically, we propose: • Excluding fluoropolymers from the restriction. • Implementing a sector derogation for non-polymeric PFAS chemicals. • Exempting PFAS chemicals used for MRO. • Providing a time-unlimited derogation for specific PFAS chemicals used in fire suppression systems. Our sector's reliance on materials from various industries necessitates these measures to prevent widespread obsolescence and supply chain disruptions. We argue that a blanket ban on fluoropolymers is disproportionate given the focus on conditions of use and risk management at manufacturing sites and end-of-life, not their inherent properties. There are more proportionate risk management options available, such as specific obligations under the Industrial Emissions Directive. A blanket ban on PFAS chemicals carries significant implications for the European Defence Technological and Industrial Base (EDTIB). This ban has the potential to undermine the EDTIB's capacity to manufacture and maintain critical defense materials and capabilities. Several EU Member States, including Sweden, as well as NATO allies and the EU itself, have placed orders and rely on the EDTIB to develop, produce, and deliver these essential defense assets. The EDTIB is currently grappling with unprecedented challenges in its supply chain and production processes. These challenges are particularly pressing as the EDTIB is actively working to provide critical equipment and materials to support Ukraine in its defense against Russia and to replenish depleted stocks. A PFAS ban would impede the EDTIB's ability to meet these demands, thereby placing the security of EU Member States and the EU itself at risk. Furthermore, the adoption of a PFAS restriction in line with ECHA's recommendations could potentially lead to an increase in the import of defense material and equipment from third countries with lower environmental and health standards. Additionally, such a restriction may hinder the development of new European technologies and capabilities. This would put the EDTIB and EU Member States at a disadvantage when competing in the global market. These challenges are especially concerning at a time when the EU is actively seeking to reduce its reliance on third countries, promote innovation, enhance competitiveness, and foster economic growth. Fluoropolymers possess unique properties ideal for high-performance applications with stringent safety and reliability requirements. Banning them compromises safety standards in aerospace and defense, as well as other industries. Regarding fire suppression, PFAS chemicals are essential alternatives to Halon, particularly in aircraft. A time-unlimited derogation is requested to maintain ongoing activities without disruptions. Lastly, we point out that reporting requirements, especially for ppb levels in articles, are impractical for aerospace and defense products, as they would necessitate testing thousands of components, which is not feasible given the current state of testing methods. In summary, we seek an inclusive and tailored approach that considers the specific needs and challenges of the aerospace and defense sector in any restriction proposal involving PFAS chemicals. |
| Answer to specific info request 1:  The dossier in Table 9 did not encompass the usage within the aerospace and defense sector adequately. The listed applications fail to comprehensively consider the distinctive needs and requirements of aerospace and defense applications concerning safety and reliability. SOFF, therefore, urges the inclusion of aerospace and defense as a distinct sector, with specific attention given to their use of PFAS chemicals within the restriction dossier. The aerospace and defense sector comprises various end-products, including: • Commercial aircraft for passenger and cargo transportation, encompassing fixed-wing aircraft and helicopters. • Military aircraft, ranging from fast jets to training aircraft, large transports, and helicopters. • Naval vessels, such as surface ships (including aircraft carriers) and submarines. • Land vehicles, including tanks, armored vehicles, communication vehicles, weapons launchers, and military personnel and munitions transport vehicles. • Weapons, munitions, and ammunition. • Space launchers, satellites, and associated ground-based support equipment. • Other defense and security systems, such as radars, communication systems, cameras, Command & Control systems, protection, and surveillance systems. Further details on the aeronautics, defense, and space sub-sectors are provided below: Aeronautics: Aeronautics products encompass fixed-wing and helicopter aircraft, involving various technologies for wing controls, propulsion, communications, flight controls, cabin equipment, fuel systems, hydraulics, oil systems, and electrical systems. It also includes ground equipment, such as air traffic control and maintenance/inspection equipment. The stringent safety and reliability requirements in this sector subject the production, operation, and MRO of products to regulatory and industry standard controls. Defense & Security: This category encompasses military aeronautics and various other capabilities vital for national and European defense and security. It includes ships, submarines, munitions, land vehicles (tanks, artillery, armored personnel carriers), air defense systems, military aircraft, as well as ground platforms for surveillance, communication, critical infrastructure protection, and ground support equipment and maintenance/inspection equipment. Due to its sensitive nature, this sector operates under strict data security controls, especially concerning technology and materials. These controls are formalized through technology export controls and security classification, preventing information disclosure except under highly regulated conditions. This consultation response, therefore, cannot disclose sensitive details of PFAS uses in military products or their operation unless these technologies overlap with non-military applications. SOFF underscores that a case-by-case defense exemption mechanism, as defined in REACH Article 2(3) for each Member State, would not be practical for a restriction of this scope, as it would necessitate thousands of exemptions in each member state. Defense exemptions also pose limitations for applications with dual uses, such as shared supply chains with non-defense-related aeronautics, and cross-border supply. Space: The EEA boasts a robust space industry involved in satellite manufacturing, launch services, and space technology development. The space sector holds strategic importance for the EEA in terms of technological independence, supporting public policies, all economic sectors, and Europe's autonomous access to space. PFAS chemicals play a fundamental role in the production, operation, and maintenance of aerospace and defense products, including the manufacture of component parts, sub-assemblies, and formulations within the aerospace and defense supply chains. Their unique properties render them well-suited for applications operating in harsh or extreme conditions with stringent requirements for reliability, performance, and safety over extended service lives. Comprehensive details regarding the widespread uses of PFAS chemicals within the aerospace and defense sector are provided in our response below. |
| Answer to specific info request 2:  Timeframe Concerns: SOFF expresses profound concerns regarding the proposed transition period and the absence of derogations for our intricate products and production equipment. Substituting PFAS compounds in our sector presents exceptional complexities, primarily driven by the imperative to employ certified and qualified materials to ensure the safety and reliability of products during their operational phase. Considering the extensive and diverse applications of PFAS across thousands of articles within our society, with ongoing data collection efforts, it is imperative to allocate sufficient time for the qualification of PFAS-free alternatives. The vast number of PFAS-containing articles and materials that necessitate replacement, coupled with stringent qualification and certification requisites, demands an extended timeframe. This applies not only to older product designs but also to ongoing design and production projects. The combination of the absence of derogations, the proposed transition periods, and the intricate verification and certification procedures specific to our sector creates an untenable situation where compliance with the draft regulatory text, if adopted as proposed, becomes nearly impossible. Importance of Differentiated Consideration: In light of the crucial role PFAS play in our industry, it is imperative that their usage remains permissible as long as their associated risks can be effectively managed, or in instances where suitable alternatives are not readily accessible. Consequently, any legislation aimed at restricting substances should not be implemented without a differentiated assessment of their uses and the resultant implications. SOFF advocates for a differentiated regulatory approach that aligns with Article 68(1) of REACH, focusing on risk-based considerations, and Article 69 of REACH, which is substance-based. Such an approach would enable a more nuanced and balanced approach to the regulation of PFAS compounds, taking into account their diverse applications and the complexities associated with their substitution. |
| Answer to specific info request 6:  The dossier submitters have overlooked the aerospace and defence sector, and the current restriction proposal inadequately addresses the uses within this sector. While some aerospace and defence uses might fall under proposed or potential derogations, the scope and duration of these derogations are deemed insufficient. Many aerospace and defence applications remain uncovered by any proposed or potential derogations. Therefore, we have provided insights into our sector's wide-ranging applications, along with information on alternative availability and socio-economic impacts, in the attached document. A summary of the key points is presented below. PFAS chemicals play an extensive role in the production, operation, and maintenance of aerospace and defence products (refer to Table 1). Among PFAS types, fluoropolymers are the most commonly used, serving as parts (e.g., seals, cables, hoses), surface treatments (e.g., paints, coatings, sealants), and components of mixtures (e.g., lubricants). Our assessment of derogations reveals that there is limited coverage for the vast majority of aerospace and defence applications. Consequently, it becomes evident that the non-use scenario's impacts, as stipulated in the current draft, would become apparent as early as 18 months after implementation, given that roughly half of our reported application areas lack coverage under proposed or potential derogations. We emphasize that the defence sector presents unique characteristics that warrant the dossier submitters' consideration. These include stringent safety and reliability requirements, the exceptionally high performance standards demanded of parts, components, systems, etc., due to harsh operational conditions, and the qualification and certification prerequisites in place to ensure safety and performance throughout a product's service life. Aerospace and defence products are also highly complex, consisting of numerous parts, components, sub-systems, and systems. A single major platform, such as an aircraft or ship, can comprise millions of parts, many of which are intricate assemblies (e.g., engines, landing gear, brake systems, fuel systems). These products boast extended service lives, necessitating the availability of spare parts consistent with the original design for decades. These sector-specific attributes render regulatory mandates for chemical substitution exceedingly challenging. In this context, the requirement to replace PFAS-containing materials would impact thousands of parts, components, formulations, and materials across diverse aerospace and defence products. Presently, there are no alternatives available that meet the stringent performance criteria demanded by these products. The list of potential alternatives presented in the restriction report (Annex E) is unsuitable for our sector, as the dossier submitters did not consider the specificities of our industry in their alternatives assessment. For example, the section outlining alternatives for the "transportation" sector does not account for varying performance requirements. Innovating new chemicals, formulations, and materials is necessary, followed by a lengthy qualification and certification process to ensure safety and reliability. For existing products, introducing new materials necessitates product redesign and recertification. To illustrate, in the case of a gas turbine engine, hundreds of PFAS-containing components would need replacement, requiring an alternative for each component before launching the recertification process for the redesigned engine. Adding to the challenge is the uncertainty surrounding R&D programs' ability to identify suitable alternatives, particularly for fluoropolymers, which are currently the sole materials possessing the requisite properties for aerospace and defence applications. It is improbable that a one-to-one alternative can be found for all current uses of PTFE, for instance. Considering the diversity of aerospace and defence products, it is crucial to recognize that the scale of the substitution requirement is unparalleled in our sector. Estimates suggest that a smaller short-haul commercial aircraft may contain approximately 400,000 - 500,000 PFAS-containing components (primarily fluoropolymers), while larger aircraft could have in excess of one million such components. Regarding RO2, which entails a ban on all PFAS chemicals with time-limited derogations for specific sectors/applications, the impact hinges on the adequacy of derogations covering PFAS uses required for the production, operation, and MRO of aerospace and defence products. If derogation coverage is incomplete or derogation periods are misaligned, the impact can be as severe as RO1. Our use and derogation mapping demonstrates that the coverage is incomplete, and the derogation periods, when provided, are insufficient for our sector. To shed light on the wider economic consequences of non-use scenarios, we refer to recent authorization applications submitted for continued use of a limited number of hexavalent chromium compounds in specific surface treatments of parts/components/systems/products by the aerospace and defence sector. This assessment provides an illustrative understanding of the economic ramifications of non-use scenarios (see Table 13 of the ASD response). Given the number of chemicals within scope and their pervasive use in aerospace and defence product production, operation, and MRO, the impact of RO2 would be catastrophic. RO2 would halt the production of new products, disrupt MRO of existing products, impede the import of products, components, and parts, and result in far-reaching economic consequences beyond job loss. For instance, considering civilian aviation, aircraft could operate within the EEA but could neither be produced, serviced, nor imported in the EEA. Similarly, in terms of national security, existing defence products (aircraft, naval vessels, land vehicles, munitions, weapons) could operate but not be serviced due to a lack of spare parts. Once existing stocks are depleted, replenishment would be impossible. New products/parts could neither be produced nor imported within the EEA, rendering defence forces unable to address security threats. It is implausible for these non-use scenarios to become a reality. Based on our assessment, it is evident that the scale of the substitution requirement, coupled with the unique characteristics of our sector, has not been duly considered by the dossier submitters. Their proposed RO2 does not encompass our sector and is therefore incomplete. Consequently, we urge the dossier submitters to revise their proposal to include our sector and take into account our considerations and requests as outlined in our general comments. |

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| 9049 | Date:  2023/09/24 16:53  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:    <redacted> | General Comments:  I have no general comments, only answers for Specific Information Requests |
| Answer to specific info request 1:  Fluoropolymers and fluororubbers are contained in many plant components in the plants we operate for energy generation and disposal (energy and waste management). PFASs are contained in particular in mechanical seals, pipe and equipment seals, and stuffing box packings. They are thus used in a wide range of equipment and machinery such as valves, pumps, agitators, pipes and containers. PFASs are also used as lubricants and components of corrosion protection systems or for internal coatings. Furthermore, fluoropolymers are also used in refrigerants in the systems we operate for building air conditioning and process cooling. |
| Answer to specific info request 2:  We ensure that in normal operation PFAS is not released into the environment from the disposal and energy supply facilities we operate. Waste and waste water are of course disposed of in accordance with the relevant regulations. At the end of their service life, the plants are disposed of in accordance with the state of the art and recycled as far as possible. This also applies to the refrigerants used. Waste containing PFAS, such as sealed gaskets or cables that need to be replaced, is also recycled or disposed of properly. As a rule, this waste can be safely disposed of in our own incineration plants, which are operated according to the state of the art. Of course, the waste of all companies located in Industriepark Höchst can also be disposed of there. |
| Answer to specific info request 3:  A recent study involving, among others, the Institute for Technical Chemistry (ITC) at Karlsruhe Institute of Technology (KIT) and Pro-K confirms that fluoropolymers do not produce measurable PFAS emissions at the end of their life when incinerated in representative European incinerators (as our own residual waste plant) and under representative conditions and therefore do not pose a risk to human health and the environment. This demonstrates that no relevant emissions are produced in the end-of-life phase when incinerated properly. Study The study "Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions" is attached under "SECTION IV. Non-confidential attachment". |
| Answer to specific info request 4:  Recycling plants are already in operation for the recycling of PFAS. Our company is aware of a recycling plant operated by the company Dyneon in Gendorf, which was developed by the research institute InVerTec (University of Bayreuth) together with the Dyneon as part of a project funded by the Deutsche Bundesstiftung Umwelt (German Federal Foundation for the Environment) to process PFAS by means of a depolymerisation process. On 26 March 2015, Dyneon GmbH opened this world's first fluoropolymer upcycling plant together with the cooperation partners Deutsche Bundesstiftung Umwelt, the University of Bayreuth and the Research Institute for Innovative Process Engineering (Invertec) in Burgkirchen. The plant is the world's first fluoropolymer upcycling plant that uses a chemical recycling process to turn old products into new ones without compromising on quality. The plant can process up to 500 t of fluoropolymer waste annually. This plant thus makes a relevant contribution to the realisation of a circular economy for fluoropolymers. (https://www.invertec-ev.de/projekte/umwelt-ressourcen-schonung/ptfe-recycling/). The process used in the plant enables significant CO2 savings in fluoropolymer production and is the first example of a true circular economy for fluoropolymers. The process was developed with funding from the BDU, the German Federal Environmental Foundation, and the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. In the meantime, Dyneon plans to phase out the production of PFAS and thus also decommission this plant. This means for the Chemical Park Gendorf that with the shutdown of this plant and all subsequent productions, about 1000 jobs will be lost. (https://www.chemietechnik.de/markt/dyneon-bleibt-die-pfas-produktion-in-gendorf-doch-erhalten-594.html) Finally, on the subject of recycling, we would like to refer to the article "Strategies for Closing the Material Cycles in the Recycling of Fluoropolymers" from "Wiley Online Library": https://doi.org/10.1002/cite.202300039). See also Non-Confidential Attachment. The article shows different processes for recycling fluoropolymers and describes their possible application to close the fluorine cycle by mechanical, chemical or raw material recycling. |
| Answer to specific info request 6:  PFAS compounds are ingredients of various components or equipment in the plants we operate. Not all uses relevant to us are described in Annex XV of the Restriction Report. Therefore, we would like to present here the other relevant applications of components with PFAS in our view and finally the socio-economic effects of a ban. For the following components or materials relevant to us, we do not recognise any classification in Annex XV: Seals mechanical bearings and sliding bushes linings of pipelines and vessels Hydraulic and other hoses Paints for surface treatment of metallic objects e.g. as corrosion coating Insulation of power cables Transformers These components require special properties such as high abrasion resistance, chemical resistance, sliding properties or temperature resistance and others. The requirements that the currently used components meet are a prerequisite for safe operation in many of the components we use, such as engines, generators, turbines, filters, pumps, compressors and apparatus such as valves or flaps, and are therefore indispensable. We started testing alternative components that do not contain PFAS at an early stage. For some of the components used, alternative materials such as ceramics or UHMW-PE are already available. However, for many applications, such as seals containing PTFE, there is no comparable alternative available today or in the foreseeable future. Therefore, we cannot operate our plants without these components or materials in an estimated period of at least 10 years. Alternatives to PFAS are also considered in the following report: https://www.k-zeitung.de/pfas-diskussion-alternativen-zu-ptfe The planned ban on the use of PFAS would mean that we would no longer be able to operate our facilities for the supply and disposal of Industriepark Höchst. We are endeavouring to examine and use alternatives to PFAS, but do not see any substitute solutions to meet our requirements in the foreseeable future. Shutting down our plants would have far-reaching consequences for our customers in Industriepark Höchst, who produce vital medicines or chemicals, for example. In "SECTION IV. Non-confidential attachment" we have attached a table with the PFAS-containing components and alternatives we have considered and their properties relevant to us. In "SECTION V. Confidential attachment" we have attached a table with the socio-economic impacts considered. |
| Answer to specific info request 7:  As new technoloiges will come, we should reconsider the usage of alternatives in about 15 Years. We estimate that it will take at least 15 years for modern hydrogen technology to do away with PFAS. |
| Answer to specific info request 8:  In "SECTION IV. Non-confidential attachment" we have attached a table with the PFAS-containing components and alternatives we have considered and their properties relevant to us. In "SECTION V. Confidential attachment" we have attached a table with the socio-economic impacts considered. In addition to our consideration, we would like to refer to the following article : https://www.k-zeitung.de/pfas-diskussion-alternativen-zu-ptfe |

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| 9050 | Date:  2023/09/24 17:03  Content:  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  Attachment:  <redacted> | General Comments:  Please have a look to the enclosed confidential pdf |
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| 9051 | Date:  2023/09/24 17:18  Content:  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United States of America  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Given the technology is still being developed, for competitive and confidentiality reasons, we are currently unable to publicly disclose certain information, as this would undermine our commercial interests. We have therefore attached all the requested information in the confidential attachment. Where possible, we have provided information in the non-confidential sections. | General Comments:  [Non-confidential response – please review confidential attachment for more details]  Our organization, a leader in mitigation and capture of harmful CO2 emissions using high performance membrane systems, welcomes the European Union's proposal for regulating PFAS-containing materials. We recognize the imperative need for comprehensive regulation in the interest of public health and environmental well-being.  While it is crucial to address and regulate certain PFAS compounds due to their well-documented environmental and health concerns, it is equally important to recognize that not all PFAS materials are created equal. Fluoropolymers have uniquely beneficial properties for CO2 capture and mitigation and have minimal impact on health and the environment. Therefore, these materials merit a separate classification within regulatory efforts when used for critical applications that support the European Union’s decarbonization goals.  In this response, we make the case that the use of fluoropolymers for use in high performance membranes for CO2 mitigation should receive a time-unlimited derogation.  Given the technology is still being developed, for competitive and confidentiality reasons, we are currently unable to publicly disclose certain information. We have therefore attached all the requested information in the confidential attachment. Where possible, we have provided information in the non-confidential sections. |
| Answer to specific info request 1:  None of the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9) align well with the proposed applications, we therefore seek the creation of a new sector and (sub-)use category. The closest sectors and (sub-)uses currently listed are: ● “Textile, upholstery, leather, apparel and carpets (TULAC)”, which includes “technical textiles”, which itself includes “high performance membranes”. However, the description of “high performance membranes” has too many qualifiers: "textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence". This definition therefore does not align well with the proposed applications. ● “Petroleum and mining”, which includes "fluoropolymer applications". However the examples given for fluoropolymer applications do not include membranes. Additionally, whilst membranes can be used in petroleum and mining applications, they can also be used in numerous other industries. We therefore propose the creation of the following sub-use: “Fluoropolymers for use in high performance membranes for CO2 mitigation”. We propose that this sub-use be applicable to a broad sector called “heavy industry”, which should include (but not be limited to): Steel & Iron, Cement & Kiln processes, Oil & Gas, Petrochemistry, Chemicals, Pulp & Paper, Glass, Power Generation, Transport. |
| Answer to specific info request 2:  [Please review confidential attachment for more details] Manufacturing phase With appropriate controls, membrane module manufacture can be done using processes that are entirely free from PFAS emissions. It is also public knowledge that all major fluoropolymer manufacturers have committed to responsible manufacturing practices in the production of fluoropolymers. This includes Chemours that plan to ‘eliminate at least 99% of PFAS air and water emissions from [their] manufacturing processes by 2030’ (see reference 1) and Solvay, which are phasing out, by 2026, the use of fluorosurfactants (see references 2 and 3), one of the largest sources of PFAS emissions in the fluoropolymer manufacturing process. Use phase Fluoropolymers exhibit a markedly different chemical structure compared to other PFAS compounds. It is well known that their strong carbon-fluorine bonds render them inert and non-reactive in most environmental conditions, which is why they have such exceptional thermal and chemical stability, the very reason they are so popular. This stability significantly reduces the likelihood of release of harmful breakdown products and therefore of harmful emissions during the use phase. This is supported by several papers. One paper by Henry et al (reference 4) concludes as follows: “This paper brings together fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data for review and assessment to show that fluoropolymers satisfy widely accepted assessment criteria to be considered as “polymers of low concern” (PLC). This review concludes that fluoropolymers are distinctly different from other polymeric and non polymeric PFAS and should be separated from them for hazard assessment or regulatory purposes. Grouping fluoropolymers with all classes of PFAS for “read across” or structure–activity relationship assessment is not scientifically appropriate.” A later paper by Korzeniowski et al (reference 5) expands on Henry et al’s study and concludes that fluoropolymers “satisfy the widely accepted polymer hazard assessment criteria to be considered polymers of low concern (PLC). [...] Further, the study results demonstrate that fluoropolymers are a distinct and different group of PFAS and should not be grouped with other PFAS for hazard assessment or regulatory purposes”. In the proposed applications, fluorinated products are deployed exclusively in industrial applications, and therefore operated in controlled environments by trained personnel. It is therefore highly unlikely that they would be mis-used in a way that could damage or degrade them so as to lead to harmful releases of PFAS-containing materials. End-of-life phase In the proposed applications, fluorinated products are deployed exclusively in industrial applications and therefore are easy to track, control, and be properly decommissioned. Several studies (references 6 and 7) have confirmed that incineration at standard conditions and using existing processes and equipment (e.g. municipal incineration) is an acceptable way to dispose of fluoropolymers with no associated harmful emissions. Reference 1: https://www.chemours.com/en/pfas-advocacy/responsible-manufacturing Reference 2: https://www.solvay.com/en/press-release/solvay-phase-out-use-fluorosurfactants-globally Reference 3: https://www.solvay.com/sites/g/files/srpend221/files/2022-06/Solvay NFS roadmap Factsheet.pdf Reference 4: Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035 Reference 5: Korzeniowski, S.H., Buck, R.C., Newkold, R.M., kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G. and Musio, S. (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: 326-354. https://doi.org/10.1002/ieam.4646 Reference 6: Krasimir Aleksandrov, Hans-Joachim Gehrmann, Manuela Hauser, Hartmut Mätzing, Daniel Pigeon, Dieter Stapf, Manuela Wexler, Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, Chemosphere, Volume 226, 2019, Pages 898-906, ISSN 0045-6535, https://doi.org/10.1016/j.chemosphere.2019.03.191. Reference 7: “Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions” |
| Answer to specific info request 3:  [Please review confidential attachment for more details] Several studies (references 1 and 2) have confirmed that incineration at standard conditions and using existing processes and equipment (e.g. municipal incineration) is an acceptable way to dispose of fluoropolymers with no associated harmful emissions. Reference 6: Krasimir Aleksandrov, Hans-Joachim Gehrmann, Manuela Hauser, Hartmut Mätzing, Daniel Pigeon, Dieter Stapf, Manuela Wexler, Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, Chemosphere, Volume 226, 2019, Pages 898-906, ISSN 0045-6535, https://doi.org/10.1016/j.chemosphere.2019.03.191. Reference 7: “Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions” |
| Answer to specific info request 6:  [Please review confidential attachment for response] |

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| 9052 | Date:  2023/09/24 17:22  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Jones Day  Org. country:  Belgium  Attachment:    <redacted> | General Comments:  Further information is provided in the Non-Confidential Attachment in Section IV. |
| Answer to specific info request 1:  Electronics and semiconductors. Further information is provided in the Non-Confidential Attachment in Section IV. |
| Answer to specific info request 2:  Further information is provided in the Non-Confidential Attachment in Section IV. |
| Answer to specific info request 3:  Further information is provided in the Non-Confidential Attachment in Section IV. |
| Answer to specific info request 5:  Further information is provided in the Non-Confidential Attachment in Section IV. |
| Answer to specific info request 6:  Further information is provided in the Non-Confidential Attachment in Section IV. |
| Answer to specific info request 7:  Further information is provided in the Non-Confidential Attachment in Section IV. |
| Answer to specific info request 8:  Further information is provided in the Non-Confidential Attachment in Section IV. |

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| 9053 | Date:  2023/09/24 17:33  Content:  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Spain  Company name confidential:  Yes  Attachment:    <redacted> | General Comments:  We are aware of the public concern for health and the environment and our company provides full collaboration for this issue. Our company manufacture Peptides as Active Pharmaceutical Ingredients (APIs) for human and veterinary use. In the manufacture, Trifluoroacetic acid is used under containtment conditions. Presently, over 80 peptide-based drugs are available in the market for the treatment of an array of diseases, including cancer, chronic pain, endocrine therapies, Hospital emergencies, diabetes, HIV infection, multiple sclerosis and osteoporosis. Some of them are included in the list of essential drugs by WHO and FDA. Further, since 2017, more than 10 peptide-based drugs have been approved by the USFDA or EMA. Of these, LupkynisTM and Zegalogue® were recently approved in 2021, while ImcivreeTM, Victoza®, LUPRON DEPOT®, Zoladex®, Sandostatin® and Somatuline® received approval in 2020. Peptides are known for their high selectivity and efficacy while still being relatively safe and well-tolerated. As a result, peptides are receiving more attention in pharmaceutical research and development (R&D), with approximately 140 peptide therapeutics currently undergoing clinical trials that could lead into new drug entities for different therapies. For the manufacture of Peptides, an essential substance is Trifluoroacetic Acid (TFA) that is used in the synthesis and purification processes and for analitical procedures. For Peptide synthesis, TFA is essential to separate the peptide chain from the polymeric support where it has been synthesized. For more than 50 years, a substitute for TFA has been searched without success. Some substances that could have similar properties are pfa’s with longer carbon chain or with more than one -CF3 groups. For Peptide purification and analysis by high performance liquid chromatography (HPLC), TFA is used as an additive to the mobile phase (same use than for medical devices. See A.3.10.1.14 PFAAs and PFAA precursors described in Annex A). The mobile phase usually has a TFA concentration between 0.1-1% (it's around 4% of the total quantity used in peptides manufacture). In the restriction Proposal it is remarked that When looking specifically at human health endpoints considered of most concern following long-term exposure of humans (i.e. carcinogenicity (Carc.), mutagenicity (Muta.), reproductive toxicity (Repr.) including effects on or via lactation (Lact.), and specific target organ toxicity (STOT RE)), 357 PFASs have a classification for at least one of these five endpoints, of which 41 are harmonised classifications (Q4 2020), see Annex B.3. for more information. Regarding the environmental hazards (hazardous to the aquatic environment and hazardous to ozone layer) 1 129 PFASs have a self-classification. According to the trifluoroacetic acid (TFA) REACH registration dossier and Chemical Safety Report (CSR), this substance does not fulfil the criteria for a PBT or vPvB substance under Annex XIII REACH. Neither does it raise equivalent levels of concern under Article 57(f) REACH. Form the above listed 7 hazards mentioned in the restriction proposal, TFA only fits among those dangerous to aquatic life, nor as PBTs, so we support that this restriction proposal should not apply to all PFAs equally. Within the PFA group, subgroups should be made according to their hazard and TFA must be out of banned uses. |
| Answer to specific info request 1:  Manufacture of Active Pharmaceutical Ingredients for medicinal products (Peptides) |
| Answer to specific info request 6:  Sector: Manufacture of active substances for Medicinal Products. PFCA used: Trifluoroacetic acid (TFA ; CAS 76-05-1). CF3-COOH. Emissions: All processes are performed in conditions of containment. Furthermore, the exhaust vapours are conducted towards abatement treatments according to the EU regulation (Directive 2010/75/EU). To comply with Directive 96/61/EU, companies anually carry out a material balance that for TFA shows that the emission to the atmosphere is practically zero and that the whole amount of TFA, after process steps of peptides manufacture, is manage as waste and in its end of life, complying with the EU legislation, it is subject to hazardous-waste incineration so in the manufacture process there is no significant emission of TFA to the environment. Key uses: Synthesis, purification, and analysis of peptides as active pharmaceutical ingredients. Alternatives/substitution: Currently, technically there aren't alternatives. Synthesis of peptides exists for more than 50 years. During this period, substances that have proven capable of being substitutes with some processes have been other PFAs with longer carbon chains or more -CF3 groups. All attempts to find different alternatives to PFA’s didn’t succeed. In the purification step, many peptides only can be purified with TFA as additive in the mobile phase (0.1-1% of concentration that only represents de 4% of manufacturing consumption). Furthermore, for each of the peptides, the change in its manufacturing process must be informed and approved by the regulatory authorities of the different countries. Which is not accepted if quality levels equivalent or higher than the current one are not achieved. Socio-economic impacts of the ban: Due to the lack of alternatives, the result of a ban on the use of TFA for the manufacture of peptides (API) would be the disappearance of peptides from the portfolio of European manufacturers. This would cause a shortage of drugs on the global market used for a wide range of hospital treatments (oncological, fertility, endocrine, hospital emergencies, diabetes, HIV infection, multiple sclerosis, osteoporosis, etc...). Many of this API’s are included in the list of essential drugs by the WHO and by the FDA. Also, would disappear peptides that are being used in the development of new drugs, causing the impossibility that many new drugs reach the market. Regarding the economic impact, Peptide manufacturers will have to close their facilities or move them to other foreign countries, causing the loss of thousands of direct jobs. For synthesis of peptides, the global market size for 2023 has been 601 millions of euros. Europe ranks second behind the United States, but projections predict that the gap will narrow in the next 10 years. Due to the ban of use for TFA, the level of losses for Europe is estimated in hundreds of millions of euros. Regarding to therapeutics peptides drugs, it is a global growing market that in 2022 represented a market size of 43.11 USD billions and projections performed by different agencies (included Bloomberg) are that the business will increase by 78% in ten years, reaching 76.83 USD billions. Peptides European manufacturers sell its products around the world. The stoppage of manufacturing by European companies would mean losses of millions globally. At this time, given the lack of availability of alternatives for the use of TFA in the synthesis, purification and analysis of peptides and the socioeconomic impact that its prohibition would generate in Europe and around the world, an unlimited derogation for such uses is required. |

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| 9054 | Date:  2023/09/24 17:45  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Denmark  Company name confidential:  Yes | General Comments:  Our company is thankful for member states providing information and restriction proposal on hazardous materials to protect the environment. Yet, with this Comment we intent to problematize the blanket restriction to prohibit PFAS in the Electronics Industries without due considerations for the nature and class of products and whether technological advances are realistic within foreseeable future. Our company is a developer and manufacturer of a special class of measurement microphones called 'Electret Microphones'. These types of microphones are especially used for measurements where traceability to the International Measurement System (SI) is needed. An electret microphone is an electrostatic capacitor based microphone that uses a permanently charged material (the electret) instead of a polarizing power supply. Without any comparison then FEP is the material of choice for electrets for microphones. Despite research in candidates for replacement materials then a substitution material is not expected in the foreseeable future. Hence a ban on specifically FEP will have huge implications for measurement microphones. |
| Answer to specific info request 1:  Electronics and Semiconductor |
| Answer to specific info request 2:  Stock: The FEP material is received in powdered form and stored in sealed bins at applicable storage area with very low risk for emission to the environment. Manufacturing: The FEP powder is mixed with a carrier paste and typically sprayed on a metal or ceramic backplate. This application is performed in dedicated protected cabinets with separate drains into sealed tanks. The tanks are collected by companies specialized in treating chemical waste according to country legislation. In-Use: For a finished electret microphone the electret part (with applied FEP) is sealed and emission to the environment is not possible with foreseeable misuse. The lifetime of an elected microphone is typically decades. End-of-Life. Microphones are categorized and is applicable in the EU for the WEEE directive. The microphones must be discarded according the country and EU legislation. Emission and yield: Each electret microphone includes a 20 microns thick FEP layer on the microphone backplate. The annual consumption for a company such as ours is less than 10 kg of FEP powder annually . Due to the nature of the process of applying a thin layer to the microphone backplate then a substantial amount of FEP is lost and collected in the sealed tanks rather than being applied. |
| Answer to specific info request 5:  For our company then quantity of FEP is less than 10kg annually. A substantial part is not applied to the microphone backplate during the application process, but is collected via separate drain in sealed tanks. During this collection process then there is no emission to the environment. The tanks are collected by companies specialized in treating chemical waste. The information regarding subsequent processes (incineration, landfilling) is not maintained by our company but follows country legislation. For the end-of-life then microphone products are within scope of the WEEE directive in the EU and must be scrapped accordingly. The information regarding incineration or landfilling during end-of-life is not maintained by our company. As the microphones are sealed during the use phase, then there is not emission to the environment during this phase. Hence as the chemical waste from in-manufacturing is collected by specialized companies and the end-of-life scrapping follows WEEE directive in the EU then there are opportunities to control general emission to the environment during the life cycles from incoming goods receival (FEP level) to end-of-life scrap (microphone level) |
| Answer to specific info request 6:  a) Covered in section 5 above. b) The FEP is used as the electret material in the special class of measurement microphones as described in the 'General Comments' sections above. For an electret microphone then the electrical charge is stored in a thin (20 microns) layer of electret material on a metal surface inside the microphone. This charge is supposed to remain in the electret layer indefinately, though high temperature and humidity can gradually reduce the charger stored in the electret layer. Currently, then FEP is by orders of magnitude the best candidate for an electret material. Currently, there are no other known materials that inherently has the same ability to maintain the electrical charge over time and at elevated temperature and humidity. Thus for the special applications for measurement microphones then no electret material alternatives currently exists. c) There are approximately 20 companies worldwide that manufactures measurement microphones. d) Currently, there are no alternatives available for electret material with physical/chemical properties that is comparable with FEP. e) R&D activities to identify and characterize replacement materials for FEP as electret has been ongoing for many years and results or advances have been presented and shared on industry level via ISE conferences (International Society on Electrochemistry). Currently, no candidates with similar properties have been identified as a replacement to FEP . f) See section e) above. g) In the event that PFAS is generally prohibited in the electronics industry then the impact on measurement microphones will be significant. If a change to other options is required by legislation then this will impact the short and long term stability of the measurement microphones. Hence the numbers of measurement errors made by users will increase. Likewise the expected lifetime of the measurement microphone will drastically decrease. This will impact the overall cost for the users of the measurement microphone. A high quality FEP electret microphone can last for decades where measurement microphones made from other electrets than FEP can currently only last for less than one year. |
| Answer to specific info request 7:  The products used as electrets in measurement microphones are not manufactured and sold as electret materials. The amount of electret material used worldwide is extremely small compared to other uses of the relevant materials |
| Answer to specific info request 8:  As explained in the sections above then the technological issue at hand is that at the moment then no other electret candidate that by orders of magnitude has similar physical/chemical properties as FEP as electret has been identified. Despite of research into the matter then it is not expected that a material that can substitute the current FEP electret material can be identified/developed within the foreseeable future, let alone the timeframe that is mentioned for time limited derogations. As alternatives then an exemption on grounds of unique physical/chemical properties for FEP as electret within the microphone industries with potentially a limit on the annual usage |

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| 9055 | Date:  2023/09/24 18:14  Content:  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Quanta Services  Org. country:  United States of America | General Comments:  The Two-Phase Immersion Cooling fluids currently being sourced from the UK are vital to our High Performance Computing business needs. There are no known alternatives that can achieve the same level of efficient cooling, therefore off setting the concern around GWP. The direct carbon and water off sets are substantial and should be considered when evaluating the Two-Phase Immersion Cooling solutions. |
| Answer to specific info request 1:  Data Center Two-Phase Immersion Cooling fluid solutions and a sub use is direct to chip applications. |
| Answer to specific info request 2:  We have worked closely with our vendor/partner in the UK and USA that have well established End-of-Life phase. |
| Answer to specific info request 3:  The specific Two-Phase Immersion Cooling fluids were carefully selected and to not pose a toxic health threat to animals or humans based on the information obtained from our vendor partners in the UK and USA. |
| Answer to specific info request 6:  I am currently unaware of any Cooling fluids that provide the high density and efficiency of the Two-Phase Immersion Cooling fluids. There are currently no know fluids that could handle the capacity of > 100KW per tank, especially when the new chip sets are increasing beyond 700W per CPU/GPU. |
| Answer to specific info request 7:  The use of traditional air cooling of large High Performance work loads, such as found in Science and Industry facilities could be more detrimental to the environment than the PFAS cooling fluids which will soon have a lower GWP. The Carbon and Water off sets (23 Million liters of water for a 1MW traditional air cooled environment compared to no chilled water plant requirement for the Two-Phase Immersion cooled environments. This is huge reason why we need to explore alternative cooling methods that allow us to manage a number of environmental factors safely. |
| Answer to specific info request 10:  We have established an Edge Data Center Research Center in Dalton, GA, USA. It is here where we intend to prove specific benefits of the Two-Phase Immersion Cooling fluids that we are currently testing from the UK and the USA. We are happy to share findings with National Research Laboratories and other similar work groups. |

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| 9056 | Date:  2023/09/24 18:21  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Jiangsu Meilan Chemical Co.,Ltd.  Org. country:  China  Attachment:    Privacy statement:  - | General Comments:  We admire the EU's continuous efforts in promoting environmental protection legislation, and we have sincerely complied with the requirements of EU chemical regulations, such as Regulation (EC) No 1907/2006 (REACH). We also conscientiously implement the relevant EU regulations related to POPs, Regulation (EU) 2019/1021 on persistent organic pollutants (POPs). But we have the following questions or different opinions regarding this PFAS proposal and hope to receive a response: 1：Please clarify the definition of PFAS substance range: Per and polyfluoroalkyl substances (PFASs) refer to perfluorinated and polyfluoroalkyl substances (PFASs). The definition of the substances involved in the bill is unclear, the jurisdiction of the bill is unclear, and it is not known how many substances are covered (approximately 10000 on February 7th at a press conference; public opinion on April 5th stated that there will be more than 10000). How many substances are they? We need a clear and clear definition. The proposal now refers to thousands, how many are they? The press conference said there were about 10000, but communication would say there were over 10000. How many were there? PFASs are used by multiple scientists, organizations, and countries to refer to different ranges of substances. The use of Per and polyfluoroalkyl substances and PFASs in EU legislation in such situations can cause confusion among the public, requiring the use of clearer and more explicit language and expressions. It is necessary to redefine and clarify the substances involved in the bill. Supporting Document 1 Content: A total of 360 organic fluorine drugs were studied and screened according to their structure, compared to 9 PFAS definitions Buck et al. defined in 2011 that 8 organic fluorine drugs met this definition (2.2%); According to the OECD (2018) definition, 5 organic fluorine drugs meet this definition (1.4%); According to the OECD (2021) definition, 107 organic fluorine drugs meet this definition (30%); 4. Gl ü ge et al. (2020) defined that 22 organic fluorine drugs met this definition (6.1%); 5. According to TURA (2021a) definition, six organic fluorine drugs meet this definition (1.7%); 6. According to TURA (2021b) definition, four organic fluorine drugs meet this definition (1.1%); 7. According to the US EPA OPPT (2021) definition, 5 organic fluorine drugs meet this definition (1.4%); 8. ≥ 1% perfluorocarbon atom definition, 337 organic fluorine drugs meet this definition (94%); 9. All organic fluorine definitions, 360 organic fluorine drugs meet this definition (100%). 2.Risks： This Annex XV report covers the risks to the environment and human health caused by the use of perfluorinated and polyfluoroalkyl substances (PFASs), and provides the enforcement effectiveness, feasibility, and effectiveness of two limiting options (ROs) as the most suitable risk management option (RMO) under REACH regulations for the identified risks Assessment of monitorability and socio-economic impacts. PFASs are a group of thousands of substances primarily manufactured by humans, applied in many fields in Europe. These applications include textile industry applications, (food) packaging, lubricants, refrigerants, electronics industry, construction, and many more fields. These substances are used as their own state (non aggregated or aggregated), as components of mixtures, and as complex (articles) products for consumption, specialized, and industrial purposes. What are the specific risks mentioned in the report, what are the environmental risks, and what are the risks to human health? Does each substance have the same risk? The PFASs mentioned in the bill do not have a specific list indicating which risks are, and we believe it is not serious. Do you have any testing reports on the risks of PFASs to the environment and human health? Have you conducted a randomized double blind controlled trial? What PFASs substances pose specific risks to which group of people? 3. Persistence: The main concern for all PFASs and/or their degradation products within the scope proposed in this restriction is the very high persistence, which greatly exceeds the very persistent standard (vP, very persistent) specified in Annex XIII of the REACH regulation. PFASs and their degradation products may persist in the environment, longer than any other human made chemicals. Further supportive concerns are their bioaccumulation, mobility, long range transport potential, plant accumulation in plants, global warming potential, and ecological toxicological effects. PFASs enter the environment through emissions during production, use, and waste stages. What is the relationship between persistence and risk? Is there always a risk when there is persistence? Is worry a sufficient reason for restriction? Are these substances all possessing these negative characteristics? Is the persistence of all substances the same? Persistence alone is not sufficient to unify PFAS into a group and evaluate its risks to human health. Abstract：An expert panel was convened to provide insight and guidance on per- and polyfluoroalkyl substances (PFAS) grouping for the purposes of protecting human health from drinking water exposures, and how risks to PFAS mixtures should be assessed. These questions were addressed through multiple rounds of blind, independent responses to charge questions, and review and comments on co-panelists responses. The experts agreed that the lack of consistent interpretations of human health risk for well-studied PFAS and the lack of information for the vast majority of PFAS present significant challenges for any mixtures risk assessment approach. Most experts agreed that “all PFAS” should not be grouped together, persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, and that the definition of appropriate subgroups can only be defined on a case-by-case manner. Most panelists agreed that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS. A tiered approach combining multiple lines of evidence was presented as a possible viable means for addressing PFAS that lack analytical and/or toxicological studies. Most PFAS risk assessments will need to employ assumptions that are more likely to overestimate risk than to underestimate risk, given the choice of assumptions regarding dose-response model, uncertainty factors, and exposure information. Part 5 Conclusion：Most of the applied assumptions (e.g., dose-additivity, equal potency) are more likely to overestimate risk than to underestimate risk (i.e., will err on the side of caution). Many experts agree that 'all PFAS' should not be classified together, and durability alone cannot be sufficient to classify PFAS into a group for evaluating human health purposes. Defining appropriate subgroups can only be done on a case by case basis. Many expert group members agree that it is inappropriate to assume that differentiated PFAS group substances have the same toxicity/virulence. Most of the assumptions used now have the problem of overestimating risks (erring on the side of being too cautious). 4.Low temperature mineralization problem： Original text: When these substances and their degradation products continue to be released into the environment, the environmental concentration will increase, as PFASs within the scope of this limitation proposal do not undergo mineralization under natural conditions. Once present in the environment, removing PFAS from surface water, groundwater, soil, sediment, and biota as much as possible is technically extremely difficult and costly. Environmental testing of PFASs indicates their widespread presence in the environment, including organisms and drinking water sources and food crops, as well as remote and primitive areas, which inevitably and irreversibly exposes contemporary and future generations. Human biological monitoring shows that PFASs are widely present in the human body, with high exposure communities showing the highest levels. Due to persistence and continuous emissions, as the environmental concentration of PFASs continues to increase, human exposure and the environment of these substances will inevitably lead to negative effects. Moreover, exposure to PFASs has high potential for intergenerational effects. Some scientists say that the geographical limitations of PFASs have been exceeded, and human biological monitoring studies have shown that mixed exposure to PFASs caused by partial leaks from different sources (such as food, drinking water, PFAS-containing products, dust, air) in the general population may already pose health risks. Low temperature mineralization can degrade perfluoroalkyl carboxylic acids, which can be extended to degrade other perfluorinated and polyfluoroalkyl substances. The degradation rate is fast, and under mild conditions, defluorination will fundamentally solve the environmental problems of fluorinated substances. The thermal decomposition mechanism of perfluoroalkyl ether carboxylic acid and short chain perfluoroalkyl carboxylic acid demonstrates the effectiveness of pyrolysis degradation of PFAS. |

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| 9057 | Date:  2023/09/24 18:25  Content:  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Request for excemption of flouropolymers due to essential use applications. Details in confidential attachment, | General Comments:  - |
| Answer to specific info request 6:  Request for excemption of flouropolymers due to essential use applications. Details in confidential attachment, |

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| 9058 | Date:  2023/09/24 18:44  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Type:  Individual  Country:  China  Attachment:    Privacy statement:  - | General Comments:  I think this undifferentiated approach of group regulation is incorrect. Fluorinated polymers as safety materials ("PLC"=low concern polymers) and the materials required for their production should be exempt from PFAS regulations or usage restrictions. The stability of fluoropolymers can be directly translated into unique and durable performance properties in many applications. For the new megatrends such as green hydrogen, 5G data transmission or e-mobility, fluoropolymers represent the suitable basis on which these innovations become possible in the first place. Fluoropolymers should be exempted from all regulatory activities under the REACH restriction. Fluoropolymers can be classified as PFAS based on their molecular structure. However, their toxicological and eco-toxicological profile is essentially different from the majority of PFAS substances. Fluoropolymers that meet the OECD criteria of PLC ( = polymer of low concern) are non-toxic, non-bioavailable, non-water soluble and non-mobile molecules and are judged to have no significant impact on the environment and humans. |

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| 9059 | Date:  2023/09/24 18:51  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  European Safety Federation  Org. country:  Belgium  Attachment:    <redacted> | General Comments:  The European Safety Federation (ESF) was founded in 1991 by national organisations each representing the manufacturers and suppliers of Personal Protective Equipment (PPE) in their country, to represent them at government level of the European Union and other European institutions and instances (ESF is member of the PPE Expert Group at DG GROW and an accredited stakeholder at ECHA). ESF focusses on PPE designed for professional use, without ignoring the consumer market. Today, ESF represents over 600 companies (manufacturers, importers, distributors and service providers), of which at least 70% are SMEs. The members of ESF and the enterprises that affiliate to the national federations are dedicated and committed to provide compliant CE certified and high quality PPE. Moreover, they link quality and service by giving expert advice and assistance in the process of risk assessment and analysis as well as training and advice in all aspects related to PPE. Supporting a safety conscious way of life is a common interest to all of us. Sustainability in all its aspects is high on the agenda of the Federation and its members, obviously without jeopardising the primary function of PPE : protecting the wearer against risks for his/her health or safety. Specifically for PFAS we continue to work with our members and the complete supply chain to raise the awareness on and understanding of the topic and encourage actions to investigate alternatives.  We do understand the reasoning behind the proposal and support the intention to restrict substances that have a proven negative effect on the health of citizens and by extension to the environment. Scientific knowledge about substances is evolving over time and obviously new insights have to be taken into account. However, careful considerations should be taken into account when it comes to proof of risks as well as to alternative solutions. It is certainly not acceptable that alternative solutions are being promoted that have not proven to be effective (as well on the functionality of the product as on the economic viability as on the sustainability.  ESF wants to emphasise that our response is not only in the interest of our members and the PPE sector in general, but also in the interest of the society as a whole, as the appropriate protection of the health and safety of citizens, both in professional and in private life, is an essential function of the concerned products.  Some further considerations :  - PPE are typically regulated under the PPE Regulation (EU)2016/425. However, a number of products/applications are excluded from the scope of the Regulation , even if the function of these exceptions is the same or similar. The exceptions are not related to the function, but rather to other applicable legislation for these specific applications or products.  - PPE represent a wide range of products and applications : o From sports to do-it-yourself to visibility vests and (electric) bicycle helmets in daily traffic (non-exhaustive list of private uses) or climbing equipment and helmets o From visibility to heat and flame to chemical to biological to mechanical to electrical to cold to noise (non-exhaustive list of types of risks for health and safety of individuals) o Chemical industry, utilities supply, renewable energy production, construction sector, textile industry, but also first responders and healthcare sector (non-exhaustive list of professional sectors where PPE are needed) o PPE specifically designed for police (maintenance of law and order) and military, even if for these applications, the products are excluded from the scope of the PPE Regulation , including use in private security services, they still have the same function and should therefore be treated in the same way. o As for the previous point, PPE for exclusive use on seagoing vessels or aircrafts are also excluded from the PPE Regulation . o Respiratory protection such as the from COVID well known FFP2 and FFP3 masks to full face masks with air supply. o Firefighting and emergency response protective clothing and equipment for both professional and volunteer forces dealing with fires, accidents, floods, landslides and other disasters. o A wide range of materials (textiles, plastics, metals, …) and components (seals, electronics, …) are used in PPE  - The PPE Regulation requires manufacturers to take the state of the art into account . The state of the art is reflected in the requirements in European (harmonised) standards. The PPE Regulation Guidelines clarifies that “Manufacturers of PPE cannot be expected to use solutions that are still at the research stage or technical means that are not generally available on the market. On the other hand, they must take account of technical progress and adopt the most effective technical solutions that are appropriate to the PPE concerned when they become available for a reasonable cost.”. This clearly obliges manufacturers to make sure that the most effective solutions are used, irrespective of whether restrictions exist or not. This legal obligation for PPE manufacturers must be taken into account in the of any substance to avoid contradiction with the PPE product legislation.  - Manufacturers of PPE are often also manufacturing similar protective equipment for military and maintenance of law and order. But also manufacturing Medical Devices (e.g. medical garments, surgical drapes, medical masks and gloves, …), workwear and other types of related products.  - Given the wide range of materials and components, as well as the number of SMEs in the supply chain, the dependence of suppliers is huge in the sector. A good part of the components are not only used in PPE but also in other types of products. An example of this would be seals that are essential in some PPE, but also in many other products.  - In terms of turnover, the PPE sector is small compared to many other. Research on the effects of and on alternatives for PFAS is focussing in first instance on the bigger application fields, not so much on PPE specifically. This also results in very limited availability of scientific studies on the impact of PFAS in PPE, as well on the side of the dossier submitters as on the side of the PPE supply chain.  - However, PPE are essential for the protection of the health and safety of citizens and lack of appropriate PPE will generate huge costs for the society, due to accidents or long health issues.  - The dossier submitters chose to group products. However, this leads to some products not being considered in the proposal. Indeed PPE are not to be limited to the TULAC group (Textiles, Upholstery, Leather, Apparel and Carpets) as was done in the preparation phase. Also the other considered groups did not take PPE into consideration. o Dossier submitters only considered textiles (TULAC – Swedish authorities), even if ESF did inform them about other types of PPE (see earlier submissions and papers - ). So, it is clear that uses and products are included in the submission without any evidence. o PPE is linked to the Regulation (EU)2016/425 which excludes a number of sectors that use PPE, but are not considered in the proposal, such as  Military – armed forces : this may include military fire fighters, but also other clothing that have similar properties as other PPE, such as chemical or ballistic protection. CBRN applications are also to be considered.  Police – maintenance of law and order : private security personnel will also use some of the same equipment (e.g. ballistic protection), but also other types of PPE that have similar properties as PPE covered in the proposal o Some PPE are covered by both PPE and Medical Device Regulations. This became clearly visible during the COVID-crisis. However, this specific situation has not been taken into account in the current proposal.  - Level playing field / fair competition between EU production and imports o Without strong enforcement, a restriction makes no sense. Indeed imported PPE and materials/components will continue to contain PFAS while PPE or materials/components made in the EU will not. This results in unfair competition for the local industry, and ultimately to the disappearance of the PPE production in the EU. o The recent health crisis showed the need for local production of PPE. So the sector needs at least protection from unfair competition. We cannot believe that the aim of the restriction is to make it more viable to import from non-EU (EEA) countries, than to produce in the EU. o If in other global regions similar restrictions as the ones in the EU are not in place, the EU suppliers will already face export difficulties as EU production with PFAS containing materials/components will no longer be possible and thus EU production will face higher costs and/or less performing products.  - EU autonomy in supply chains : in view of the above remarks concerning fair competition there is a strong fear in the PPE supply chain that without derogations, it will become as good as impossible for the PPE supply to continue to work in the EU and certainly not to increase the autonomy of the EU for PPE that are critical for health or geopolitical crises.  - Enforcement of the restriction is crucial. This also includes the need to clear methods and interpretations of PFAS content in products. o Analytics methods (see also Question 10) o We see cross-contamination in production and testing (materials not containing PFAS contaminated by PFAS in e.g. • the tubing systems in the production machines, • PPE in use contaminated with PFAS, e.g. when used in activities involving products with PFAS (e.g. end-of-life treatment), • After finding PFAS in products that are not supposed to contain PFAS, a manufacturer made further analysis and came to the conclusion that the samples tested were contaminated with PFAS due to the fact that the water in the laboratory contains PFAS. So leading to false positives.  - Consequences for society if effective PPE are not available : o direct consequences for health and safety of users of less effective PPE and thus for society as a whole (e.g. healthcare costs, but also effects on mental health and wellbeing in general). o But also : if e.g. firefighters, first responders, police, military cannot be efficiently protected against the risks they might encounter, this will lead to not operating in unsafe situations and thus higher risks for the population that need urgent help. o Is it acceptable for society to take a step back in terms of protection of health and safety of individuals and to what cost ? this is also valid for industry and healthcare  - PPE manufacturers fear that if PFAS is widely restricted, producers of PFAS will decide not to produce anymore or make them no longer available in the EU. Even with a justified exemption for certain PPE, that would still mean that materials/components would no longer be available and therefore make the needed PPE no longer available.  - Current existing or proposed restrictions for specific types of PFAS take already to some extend the specificity of PPE into account. o Chemicals list in Annex A (elimination)  PFOA (C8) – derogation for PPE ended 4/7/2023  PFHxS (C6) – no specific derogation for PPE o Chemicals list in Annex B (restriction)  PFOS (C8) – no specific derogation for PPE o Chemicals proposed for listing  Long chain PFCAs (C9-C21) o Commission proposal for restriction of PFHxA (C6) – PPE derogations are included in the proposal  - The total life cycle of PPE has to be taken into account : o Efforts are made by PPE manufacturers to offer the highest level of durability for many of the products, of course taking into account the expected use of the PPE. Durability is a key element for sustainable PPE and thus cannot be ignored. o Depending on the type of PPE and the type of PFAS used, it might be necessary to re-activate/re-apply a finish to guarantee the needed protection level during the complete life cycle. This means that it is essential that the necessary products remain available for this step, not also during the derogation period, but even for an additional period. If that is not the case, the derogation period is de facto shortened as it will be impossible to maintain the protective characteristics of the PPE during the use phase. o The same remark is also valid for spare parts containing PFAS. Often the components containing PFAS need at some point a replacement during the life cycle. If these spare parts would no longer be available due to the PFAS restriction, that would mean that PPE that would still be functional for a longer period, would have to be disposed of, thus leading to unnecessary burden for the environment. o Contamination during the production phase of materials/components is a factor that needs to be taken into account. o During the use phase of PPE, it is very well possible that there is contamination with PFAS. This leads to challenges for the cleaning/decontamination process during the use, but certainly also for the end of life processing of the PPE. The contamination is not always predictable, which means that either all PPE where there is suspicion of PFAS contamination need to be treated separately or easy cost-effective methods must be available to test the presence of PFAS before the end of life processing. o Research is necessary to fully understand all effects on e.g. the ageing and the evolution of the protective properties during the life cycle of the PPE when using alternatives  - The PPE suppliers are committed to work towards solutions – research within the complete supply chain is ongoing, but needs more support and time to arrive to acceptable alternatives for all applications. In order to encourage this, ESF is working together with other associations such as e.g. FPP4EU/Cefic (chemical industry), Euratex (textile and clothing), ETSA (textile services), CEC (footwear). The contributions of those trade associations need to be considered as complementary to our own.  - Several companies from our sector participated in Ricardo study commissioned by CEFIC “Economic analysis of the impacts of a REACH restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances”. The results of this study should be considered as complimentary to this ESF contribution.  - Obviously, also individual companies active in the PPE sector submitted feedback to the consultation, often including confidential information. These are not necessarily repeated in the ESF contribution, but certainly contain additional information. |
| Answer to specific info request 1:  - Only in the TULAC sector (including professional apparel, technical textiles, leather), PPE have been considered. However, PPE are not limited to the TULAC sector. This means that some PPE products have not been considered at all. o See Question 6 below for the missing uses. o PPE are not limited to professional use, but are also used by consumers to protect themselves in e.g. do-it-yourself or leisure activities. See definition of PPE in the PPE Regulation (EU)2016/425 and the earlier general comment. o In communication with the dossier submitters, we already indicated that not all PPE fit in the TULAC sector. This information was knowingly ignored by the dossier submitters. See documents submitted earlier in annex - Textiles o The term ‘textiles’ is not clearly defined, which will lead to potential differences in interpretation. E.g. in the PPE segment of protective textiles, these should not be limited to woven or knitted fabrics but more broadly also to :  Non-woven  Coated  Laminated  Ropes – braided or constructed otherwise (e.g. used in PPE against falling from heights) o An important number of PPE products or combinations could be seen as hybrid because they contain textiles and or other materials/components (e.g. plastics, electronics) that may contain PFAS needed for the protective function. The wording of the derogation needs to be clear on the terminology to ensure that all PPE are meant and not only those included in the TULAC group.  Assembly e.g.:  Visors for heat & flame protection (e.g. electric arc flash protection, firefighting, foundry workers)  Footwear including textiles  Helmets including textile to be able to fix the helmet on the head or providing padding.  CBRN protective equipment  Ensemble e.g.  Chemical protective garment e.g. with/without incorporated visor, with/without (connectors for) gloves, with/without connectors for respiratory protective devices, with/without footwear or bootees.  Layered clothing system  Helmet with or without visor  Smart PPE including electronics  PPE with integrated electronics (e.g. hearing protectors with integrated communication system) - Care should be taken to include in derogations all concerned products. Not only those CE marked to the PPE Regulation (EU)2016/425, but also those products that are excluded from the scope (e.g. military, maintenance of law and order, seagoing vessels and aircrafts). Also a note needs to be made that the PPE Regulation foresees the possibility for PPE without CE marking, this is e.g. the case for products in the design phase that are for wearer trials, for demonstration or used for testing/certification procedures. These must be treated in the same way as fully CE marked PPE. |
| Answer to specific info request 5:  - Care should be taken to include in derogations all concerned products, not just textile materials. Not only those CE marked to the PPE Regulation (EU)2016/425, but also those products that are excluded from the scope (e.g. military, maintenance of law and order, seagoing vessels and aircrafts). Also a note needs to be made that the PPE Regulation foresees the possibility for PPE without CE marking, this is e.g. the case for products in the design phase that are demonstrated or used for testing/certification procedures. These must be treated in the same way as CE marked PPE. - See documents in annex with feedback to Swedish authorities dated 17/10/2021 which contain proposals. - Appendix A.3.3. (table A.78) of the proposal only contains protective clothing, gloves (as dealt with in the CEN TC 162) and some footwear. This strengthens the uncertainty concerning the definition of textiles in this context as also other PPE are made of or contain textiles. A known example are the single use FFP masks. - The proposed derogation is limited to category III (a) and (c). However, as demonstrated, oil repellence is crucial for the protection against other risks, not only in category III for use in industry (welding, heat and flame, electric arc, chainsaw, …), but also in military and police applications (see e.g. CBRN, Molotov cocktails, ballistic protection) and also for protection against cuts from chainsaws (category III (j)) and in all heat and flame protection as well as in visibility clothing. In the last examples, the effect of oil repellence is indirect, but essential. Indeed the properties of the materials will be severely negatively influenced by possible absorption of oily substances and therefore require protection against these oily substances. Till today, this is only feasible using PFAS at least C6 (mostly based on PFHxA) containing finishes or materials. See confidential information provided to ESF by individual companies on repellence testing on fire fighter garments, which is also valid for other types of garments where repellence for chemicals is a requirement. - For textiles (garments, gloves and even footwear) the major needs for PFAS, be it as finish are as one of the layers in the system, are repellence and barrier to penetration. - Chemical and biological agents o See earlier provided information for specific PFAS restriction (e.g. C8 versus C6 chemistry). o CEN TC 162 WG 2 provided material specifically for firefighter equipment. o Even with the transition from C8 to C6 chemistry for the finish of textiles, the repellence and penetration performance with butan-1-ol and o-xylene are diminished. Non-C6 based repellence finishes have so far proven to be effective for water, water based chemistries (such as weak acids and bases) but not effective against oils, alcohols and other organic solvents or chemical (including gasoline and other petroleum products). o Alternative PFAS free solutions manage to obtain acceptable repellence/penetration levels for relatively weak acids and bases, but not for concentrated acids and bases, as well as for solvents or oily substances. Even when it is possible to claim type 6 chemical protection with these PFAS free alternatives, the needs for a part of the industry (and certainly for firefighters) are not met with these finishes. o If a protection against a wide range is needed, PFAS are even more critical to achieve the required level of protection. In the case of protective gloves a remark must also be made concerning dexterity and mechanical resistance. Even if alternatives would offer a similar level of protection than the current PFAS solution, if dexterity and mechanical resistance is lower (which is currently the case for the alternatives that are being considered), the gloves are not suitable for use. Indeed less dexterity means that the wearer is not able to perform the job as required and less mechanical resistance means that chances that the glove will tear or get punctured during use is unacceptably high, leading to safety risks. - Oil repellence and penetration : see above - Water : no need for PFAS, alternatives are available - Situations where combination of repellence/penetration with heat and flame retardance is necessary, are even more critical for the use of PFAS solutions to ensure that the heat and flame retardancy, which is the primary protection is not compromised by soiling from oil, petroleum products or other flammable solvents. - For the alternatives, durability has to be a key element. Shorter life time of PPE leads to higher volumes of waste, which of course has to be avoided as creating new risks and challenges. - Remark : while we recognise that referring in the text of the proposal to (European) standards can be useful to clarify the products involved, it should be avoided in final proposals as standards do evolve (newer versions, different references, …), which in the longer term could lead to interpretation issues. It also has to be taken into account that the requirements in the standards are primary requirements, secondary levels of protection are usually not included. - Proposal for text for derogation : - By way of derogation, paragraphs 1 and 2 shall not apply to: b. Personal protective equipment (PPE) as well as textiles and other materials and components used in PPE intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, and where the functionality (protection of the wearer of the PPE and/or protection of the protective function of the PPE) requires the use of PFAS as part of their (i) manufacturing process, (ii) finishing or repellence, or (iii) components or parts, until 13.5 years after EiF; c. Personal protective equipment (PPE) as well as textiles and other materials and components used in PPE in firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF; d. similar to the articles referred to in paragraph 5b and 5c, the articles with similar function but excluded from the scope of the PPE Regulation (EU)2016/425. This includes PPE specifically designed for maintenance of law and order and armed forces (including private or semi-private security personnel) and for exclusive use on seagoing vessels or aircrafts, until 13.5 years after EiF; e. similar to the articles referred to in paragraph 5b and 5c and 5d, these articles in the design phase, e.g. samples for testing, wear trials or demonstrating, until 13.5 years after EiF; f. impregnation agents for re-impregnation and spare parts of articles referred to in paragraph 5b, 5c, 5d and 5e until 13.5 years after EiF (note : this point might require a longer period to allow for the products to be used till the end of the expected life. |
| Answer to specific info request 6:  - See information provided to Swedish authorities (annexes “Responses to questions – meeting with PPE companies (protective clothing)”, dated 17/10/2021 and “Contribution 2nd consultation on a restriction for PFAS”, dated 17/10/2021 - PPE other than those included in the TULAC group were not at all or only partially considered so far. For PPE, protection against risks given in the following list need to be considered, not only in the TULAC group. o the risks as in the PPE Regulation annex I for cat III :  substances and mixtures which are hazardous to health – only considered for TULAC  atmospheres with oxygen deficiency – only considered for TULAC  harmful biological agents – only considered for TULAC  ionising radiation – only considered for TULAC  high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C – only considered for TULAC  low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less – only considered for TULAC  falling from a height – only considered for TULAC – PFAS not essential  electric shock and live working – only considered for TULAC  drowning – only considered for TULAC  cuts by hand-held chainsaws – only considered for TULAC  high-pressure jets – only considered for TULAC  bullet wounds or knife stabs – only considered for TULAC  harmful noise – only considered for TULAC. o Other risks / products than category III, as well as those PPE excluded from the PPE Regulation (see also general comments on this aspect) – none of those were considered by the dossier submitters  Static electricity  Mechanical action • Vibrations • Friction • Impact with other persons or objects (e.g. falling objects, sports applications such as different types of protectors for e.g. bicycle or horse riders) • Superficial mechanical injury • Rescue equipment and similar such as anti-avalanche airbags  Motorcycling equipment (including helmets)  High visibility equipment – partly considered for TULAC  Protection against UV radiation  Swimming/diving goggles and masks  Ski goggles / helmets  Equipment for different types of leisure activities (e.g. cycling)  Welders equipment (including welding screens)  Protection against insects / animals (e.g. tick bites, beekeeper equipment, …)  Weather conditions / adverse atmospheric conditions  Anti-slip footwear  CBRN protection  Respiratory protection, see e.g. COVID protection up to full face masks. Not all of the above require PFAS, however some do. Further research is necessary for all the applications. See also the general comments provided. - PFAS free PPE might get contaminated with PFAS during the production and use phase – see general comments provided - Proposal for text for derogation : - By way of derogation, paragraphs 1 and 2 shall not apply to: b. Personal protective equipment (PPE) as well as textiles and other materials and components used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, and where the functionality (protection of the wearer of the PPE and/or protection of the protective function of the PPE) requires the use of PFAS as part of their (i) manufacturing process, (ii) finishing or repellence, or (iii) components or parts, until 13.5 years after EiF; c. Personal protective equipment (PPE) as well as textiles and other materials and components used in personal protective equipment (PPE) in firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF; d. similar to the articles referred to in paragraph 5b and 5c, the articles with similar function but excluded from the scope of the PPE Regulation (EU)2016/425. This includes PPE specifically designed for maintenance of law and order and armed forces (including private or semi-private security personnel) and for exclusive use on seagoing vessels or aircrafts, until 13.5 years after EiF; e. similar to the articles referred to in paragraph 5b and 5c and 5d, these articles in the design phase, e.g. samples for testing, wear trials or demonstrating, until 13.5 years after EiF; f. impregnation agents for re-impregnation and spare parts of articles referred to in paragraph 5b, 5c, 5d and 5e until 13.5 years after EiF (note : this point might require a longer period to allow for the products to be used till the end of the expected life. |
| Answer to specific info request 10:  - Single material or single product : PPE contain several materials, it needs to be clarified how the PFAS content has to be determined in such cases. - Multiple articles can be made available on the market as a single PPE product (e.g. complex chemical / CBRN suits). Also for these cases, clarity on how to determine the PFAS content is necessary. - Degradation / contamination during production or use of PPE products : at what time in the life cycle must the PFAS content be determined ? - It is necessary to consider the source of PFAS measured in/on products. The manufacturer of the PPE is not necessarily the source – see cross contamination but also contamination in testing facilities that can have an influence on the measurement. See confidential test reports in annex - Further clarification on the accuracy of testing of thousands of PFAS substances in thousands of different products is necessary. - The analytical methods are key for the enforcement of any restriction. If it is impossible to measure correctly, a restriction only leads to frustrations at all levels of society. o A PFAS report by the US National Science and Technology Council also acknowledges the issue with analytical methods when it comes to PFAS testing and outlines a series of actions in order to address research gaps See : https://www.whitehouse.gov/wp-content/uploads/2023/03/OSTP-March-2023-PFAS-Report.pdf o A report commissioned by the Norwegian Environment Agency looked into the available analytical methods for 17 specific uses/ matrices and showed the current limitations of the standard methods available for measuring PFAS. It concluded, amongst others, that: (i) no standards available for total organic fluorine methods or the total organic precursor assay, (ii) Total fluorine methods will not provide concentration for single substances, (iii) no standard methods found to measure specific PFAS in some uses (e.g. electronics and electronic equipment incorporating semiconductors, F-Gases and refrigerants, medical devices and medicinal products, cosmetics, oil gas and mining, metal plating, flame retardants and resins), (iv) etc. See : http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1642999&dswid=-5818 |

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| 9060 | Date:  2023/09/24 18:54  Content:  Scope or restriction option analysis  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  As a manufacturer of compressors, refrigerated compressed air dryers and compressed air filters for industrial use, we would be massively affected by a comprehensive PFAS restriction with regard to all our product groups.  We fully support the consultation contributions submitted by the manufacturers' association Pneurop, in the preparation of which we were involved, in particular the consultation contributions of Pneurop PN2 - Compressors and Pneurop PN14 - Air Treatment, which are particularly relevant for our product groups.  The impacts of a comprehensive PFAS restriction identified in these Pneurop consultation submissions are all applicable to our product range, with the strongest impacts expected in the following areas:  1) Restriction of the use of fluoropolymers (e.g., PTFE, FPM, PVDF, FEP, PFPE) as a base material, component or coating of machine elements such as seals, bearings, and hoses. 2) Restriction of the use of PFAS as a component in lubricants for compressors. 3) Restriction of the use of F-gases, which fall into the PFAS category, in refrigeration circuits of refrigerated compressed air dryers.  In this regard, we would like to provide the following information in addition to Pneurop's consultation comments. This contribution relates to fluoropolymers in machine elements such as seals, plain bearings and hoses.  For cost reasons, such machine elements made of/with fluoropolymers are only used for particularly demanding applications in which a long service life, good dimensional stability, high elasticity and/or permanently good sliding properties must be achieved under the influence of high temperatures, high oxygen partial pressure, aggressive chemical impurities in the air to be compressed and/or high mechanical stresses (e.g. as a result of pressure and pressure cycling). For less demanding service conditions, less expensive polymers that do not fall into the PFAS category are used anyway.  No alternative materials with the same properties available:  Currently, there are no alternative materials available for such machine elements that cover this range of applications, especially in the combination of stresses and requirements, even approximately with the same service life and reliability.   Small proportion by weight, but of high importance:  The machine elements in our products, which are made of fluoropolymers, account for only a very small proportion of the total weight (indicatively well below 0.0005 w/w), but have a high significance for reliability, availability, durability and minimization of maintenance requirements.   Negative impact on service life, reliability, maintenance intervals and competitiveness:  These machine elements are deeply integrated into our products, which means that, unlike typical maintenance parts, they are not easily accessible or easy to replace. On the contrary, replacing these components usually requires extensive disassembly and reassembly of major subassemblies. This is inherent and could only be changed to a small extent by extensive and costly redesign of the products.  A significantly shortened service life of these machine elements, as would occur if materials with significantly poorer properties were to be used due to comprehensive restrictions on PFAS, would therefore not only result in shorter maintenance intervals, but also in a significant increase in the maintenance effort per maintenance cycle.  In industrial plants, which are our most important customers, the availability of compressed air in the required quantity and quality plays an essential role because production can come to a standstill if the compressed air supply is disrupted. The reliability and availability of products, especially compressors, therefore plays an essential role.  In the event of a comprehensive restriction of PFAS, our products would not be competitive in markets outside the EEA, where the above-mentioned machine elements may continue to consist of or contain PFAS.   Improving recycling as a better alternative instead of restriction:  Almost all of our products are subject to the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU. This regulatory framework provides good conditions for collecting, safely disposing of or recycling the machine elements containing PFAS at the end of their service life.  Furthermore, our products consist to a large extent of valuable and easily recyclable materials (e.g. steel, copper, aluminum), so that there is an economic interest in recycling at the end of the service life.  We therefore recommend not to restrict the use of fluoropolymers for machine elements such as seals, plain bearings and hoses for use in compressors, refrigerated compressed air dryers and compressed air filters, but to introduce additional measures to improve labeling, traceability and recycling of such machine elements.   Time required for qualification of alternatives:  For us as a machine manufacturer, machine elements made of/with fluoropolymers are mostly purchased parts. There are several stages in the supply chain between material production and use in our products.  The development of alternative machine elements without PFAS starts with material development. This is followed by the development of the machine elements. We assume that several years are already required to bring possible alternatives this far.  After that, these machine elements must be qualified for use in our products. Tests in the laboratory or test field have only limited significance in this respect. Accelerated tests under artificially aggravated operating conditions alone are not meaningful. Ultimately, comprehensive field tests in real products, under numerous different real operating conditions and over long periods of time are required.  We assume that at least 5 years after the availability of machine elements made of alternative materials are required before meaningful results from field tests are available. And meaningful results are not necessarily a confirmation of suitability; the opposite is equally possible.  If the use of fluoropolymers for machine elements such as seals, plain bearings and hoses for use in compressors, refrigerated compressed air dryers and compressed air filters is not permitted to remain, we therefore recommend transition periods of at least 10 years. |
| Answer to specific info request 6:  Fluoropolymers in machine elements such as seals, plain bearings and hoses used in compressors, refrigerated compressed air dryers and compressed air filters for industrial use. |

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| 9061 | Date:  2023/09/24 19:26  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  European Coil Coating Association (ECCA)  Org. country:  Belgium  Attachment:  <redacted>  Privacy statement:  Members provided information to ECCA on a confidential basis. | General Comments:  THIS IS A REPEAT SUBMISSION AS NO FORMAL CONFIRMATION (VIA EMAIL) WAS RECEIVED FOR THE SUBMISSION MADE ON THE 22ND SEPTEMBER.  The current proposal contains no derogations and a transition period of 18 months for coil coating applications of the PTFE fluoropolymer. ECCA requests that this fluoropolymer is excluded from the proposed PFAS restriction on the basis that: (a) PTFE additives coatings are used in coil coated products to provide the required levels of formability and surface hardness. These properties facilitate the use of the products in the supply chain and reduce waste and rework. (b) Whilst there are some alternative additives products e.g., polyolefins that could be used to replace these fluoropolymers in some applications. There are no cost-effective alternative products that will meet the performance of PTFE in demanding market applications e.g., building facades. (c) A restriction on the use of PTFE in coil coating applications will require the paint companies and coil coaters to undertake a large (greater than 10,000 products) programme of reformulation and revalidation to establish the appropriate alternatives that could be used to provide an equivalent level of performance. This programme will consume high levels of technical resource and divert this invaluable resource away from other important topics such as decarbonisation. This reformulation programme would not be completed within 18 months proposed in the restriction. (d) The PTFE-containing products are recycled at the end of life through established supply chains which result in the organic coating (and the fluoropolymer additive) being incinerated at high temperatures in primary metal manufacturing processes. These processes are subject to the Industrial Emissions Directive, and they deploy extensive abatement technologies to deal with a wide range of hazardous substances. The incineration and abatement technologies eliminate fluoropolymer or PFAS emissions from the recycling of these prepainted metals. This request is consistent with the UK Government who have recently published their detailed RMOA on the restriction of PFAS chemicals following detailed consultation with the various stakeholders. Should ECHA decide to retain fluoropolymers within the proposed restriction then ECCA requests that a 10-year (+18 months) derogation is granted to this application of PTFE. This will provide the industry with a suitable period time in to develop new paint formulations systems that meet the technical performance of the current PTFE-containing products. |
| Answer to specific info request 1:  The comments in this document apply to the coil coating sub-sector of the construction sector as defined in Table 9 of the Restriction Proposal. Coil coating is also defined as a sub-use sector of the metal industry sector in Table A.57 with section A.3.14 (Construction Products of Annex A). Coil coating is discussed in section E.2.13 (Construction Products) of Annex E in the section titled “coil coating” on page 405. The comments apply specifically to coil coated products containing PTFE additives for the construction, appliance, and other markets. Where PTFE = polytetrafluoroethylene. |
| Answer to specific info request 2:  see attached document |
| Answer to specific info request 3:  see attached documen |
| Answer to specific info request 4:  see attached documen |