**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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| 9517 | Date:  2023/09/25 20:26  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Description of analytical methods  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Korea, Republic of  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  included confidential laboratory tests and to protect the info | General Comments:  Please find the attached opinion information |
| Answer to specific info request 1:  Please find the attached opinion information |
| Answer to specific info request 2:  Please find the attached opinion information |
| Answer to specific info request 3:  Please find the attached opinion information |
| Answer to specific info request 4:  Please find the attached opinion information |
| Answer to specific info request 5:  Please find the attached opinion information |
| Answer to specific info request 6:  Please find the attached opinion information |
| Answer to specific info request 7:  Please find the attached opinion information |
| Answer to specific info request 8:  Please find the attached opinion information |
| Answer to specific info request 9:  Please find the attached opinion information |
| Answer to specific info request 10:  Please find the attached opinion information |

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| 9518 | Date:  2023/09/25 20:25  Content:  Scope or restriction option analysis  Type:  Individual  Country:  Germany | General Comments:  Der gegenwärtige EU PFAS-Verbotsvorschlag beschreibt das weltweit weitreichendste Beschränkungsvorhaben für eine sehr große Gruppe von existierenden und auch noch nicht bekannten PFAS. Von den etwas mehr als 10.000 bereits bekannten Stoffen ist nur ein kleiner Teil wirtschaftlich relevant. Der überwiegende Teil dieser Stoffe wurde nur im Labor- oder Technikumsmaßstab hergestellt, hat wirtschaftlich keine Bedeutung erlangt, wird kontrolliert aufbewahrt oder sicher entsorgt (Sondermüllverbrennung mit vollständiger Mineralisierung). Die Eigenschaften der wirtschaftlich nicht relevanten Verbindungen sind oft nur sehr wenig untersucht. Sollten diese Stoffe wirtschaftliche Bedeutung erlangen, würden Sie gemäß der bewährten REACh-VO einem individuellem Registrierungsverfahren unterworfen und näher geprüft und beurteilt werden.  Für alle der mehr als 10.000 PFAS wie auch für wirtschaftlich relevante PFAS-Gruppe der PFAS gilt, dass sich diese Substanzen in ihren Eigenschaften erheblich unterscheiden können. Neben außerordentlich gefährlichen und schlecht zu kontrollierenden PFAS, deren Notwendigkeit in vielen Fällen bezweifelt werden muss und deren Verbot daher auch angemessen und geboten ist (z.B. PFOA, PFOS, etc.), gibt es viele unbedenkliche PFAS, die sicher hergestellt, verwendet, entsorgt oder vernichtet werden können. Gleichzeitig tragen solche PFAS einen hohen technischen, gesundheitserhaltenden / gesundheitswiederherstellenden, umweltschützenden und gesellschaftlichen Wert in sich, (z.B. polymere PFAS im Sinne von Polymers of Low Concern wie PTFE Polytetrafluorethylen, PFPE Perfluorpolyether, Fluorkautschuke, etc.).  Das Verbot aller PFAS nach spätestens 13,5 Jahren wird immer wieder damit begründet, dass man diese Stoffe nicht alle einzelnen untersuchen könne und es wird der Eindruck erweckt, dass sich die Stoffe nicht in Untergruppen fassen lassen. Gleichzeitig wird allen PFAS unzulässigerweise das Worst-Case Profil von Stoffen wie PFOA, PFOS etc. übergestülpt. Die PFAS ließen sich aber sehr wohl mittels struktureller und funktionaler Betrachtungen und Methoden wie QSAR (Quantitative Structure-Activity Relationship) in Gruppen einteilen, die über den Rech Read-Across-Ansatz gemeinsam bewertet werden können. Der Untersuchungsaufwand würde damit um ein Vielfaches gesenkt werden können.  Weiterhin wird die Dringlichkeit des umfassenden Verbots damit begründet, dass PFAS in der Umwelt und in Lebewesen nachweisbar sind. Die wirtschaftlich nicht relevanten PFAS wird man nicht finden und von den wirtschaftlichen relevanten PFAS werden es nur die sein, deren Bedenklichkeit im Wesentlichen schon bekannt ist und für die schon Beschränkungen und Verbote bestehen oder gerade entwickelt werden (z.B. PFOA, PFOS). Andere Stoffe wird man zwar in der Umwelt finden, wegen ihrer Eigenschaften sind sie teilweise weder bioverfügbar, noch bioakkumulierbar noch toxisch (z.B. PTFE, PFPE). Eine Summenanalytik über den Fluorgehalt kann nicht differenzieren und ist daher nur sehr eingeschränkt nutzbar.  Der Verbotsvorschlag lässt außer Acht, dass Gewinnung, Verarbeitung, Nutzung und Entsorgung von PFAS einem ständigen Verbesserungs- und Innovationsprozess unterliegen. So lassen sich PFPE schon seit vielen Jahren völlig emissionsfrei herstellen und benötigen auch keine niedermolekularen PFAS-Emulgatoren. Und für die Herstellung von PTFE arbeitet die Industrie an der Eliminierung PFAS-haltiger Prozesshilfsmittel. Selbst im Bereich der PFAS-Altlastenbeseitigung und Trinkwasseraufbereitung wurden in den letzten Monaten Methoden entwickelt, die selbst Substanzen wie PFOA aus dem Trinkwasser entfernen können, einige Methoden erlauben sogar den Abbau von PFAS. Aktuelle Studien zeigen zudem, dass PFAS selbst in Hausmüllverbrennungsanlagen, die den EU-Standards genügen, sicher mineralisiert werden können. Das allein schon stellt die häufig verwendete Klassifizierung der PFAS als „Ewigkeitschemikalien“ in Frage: ein Begriff, der wissenschaftlich keine Aussagekraft hat, aber geeignet ist, diffuse Ängste in der Bevölkerung und bei politischen Entscheidungsträgern zu wecken und zu verstärken. Mit dem nahezu unumkehrbaren Verbot schneidet sich die EU von der technologischen Entwicklung in der Welt ab.  Weiterhin verlässt der Verbotsvorschlag bewährte Ansätze wie die risikobasierte Bewertung von Chemikalien. Stattdessen werden nur Gefährlichkeitsmerkmale angeführt und neue „gefährliche“ Merkmale wie die Persistenz herangezogen, die für sich allein ein Verbot rechtfertigen sollen. Daten zu Emissionen, Immissionen, Migration, Exposition, Bioverfügbarkeit, etc., mit denen man das Risiko einer Chemikalie beurteilen kann, bleiben unberücksichtigt. Damit opfern wir wertvolle Chemikalien, obwohl wir in der Vergangenheit gelernt haben, auch mit gefährlichen Chemikalien verantwortungsbewusst und sicher umzugehen, wenn sie uns nutzen.  Die vielfältige Verwendung der überwiegend hochpreisigen PFAS, oft in sehr geringen Mengen, aber kritisch für die Funktion von Materialien und Komponenten in unzähligen Geräten, Maschinen und Anlagen ist kaum überschaubar. Oft sind es kleine, hochspezialisierte Firmen, deren Produkte ohne PFAS extreme Leistungseinbußen erleiden oder unbrauchbar würden. Die Folgen eines so umfassenden und schnellen Verbots sind für diese Firmen, die EU und auch Nicht-EU-Länder kaum abschätzbar. Es gibt zudem immer noch Firmen, die nicht einmal wissen, dass funktionskritische Komponenten in ihren Produkten oder Produktionsanlagen PFAS enthalten, und 18 Monate nach Inkrafttreten des Verbots wesentliche Geschäftseinbußen hinnehmen müssen oder gänzlich vom Markt verschwinden.  Gleichzeitig werden Produkte, die unter Zuhilfenahme von PFAS hergestellt werden, ins Nicht-EU-Ausland verlagert. PFAS-haltige Maschinen werden künftig dennoch im Nicht-EU-Ausland gefertigt und verkauft. Die mit solchen Maschinen hergestellten, zwar PFAS-freien Produkte müssten wir dann in die EU importieren. Das liefe dem EU Green Deal Prinzip, die Abhängigkeit von Nicht-EU-Ländern und komplexen Lieferketten signifikant abzubauen, völlig entgegen. Bereits jetzt ist schon absehbar, dass Länder wie China, Indien, USA und selbst das United Kingdom, dem EU-Ansatz eines umfassenden PFAS-Verbots nicht folgen und Nutznießer des EU-PFAS-Verbots sein werden. PFAS werden vermehrt in Ländern verwendet werden, die eine wesentlich rückständigere Chemikaliengesetzgebung haben, womit insbesondere mobile PFAS trotzdem über die Umwelt in die EU gelangen werden. Zudem ist anzunehmen, dass über komplexe Aggregate oder schlecht analysierbare Materialien/Produkte unerlaubt weiterhin PFAS in die EU importiert werden. Die zahlreichen und nicht enden wollenden Produktbeanstandungen bei Consumer-Produkten aus Nicht-EU-Ländern (z.B. wegen Cr(VI), cancerogener Stoffe, etc.) zeigen, wie schwer diese Importe zu verhindern sind.  Die Tatsache, dass im Verbotsvorschlag PFAS-haltige Ski-Wachse, die technisch leicht ersetzbar und deren Emissionen im Vergleich zu anderen PFAS-haltigen Produkten gering sind, als eigenständige Verwendung aufgeführt sind, während z.B. unverzichtbare Materialien für den Chemie-Anlagenbau überhaupt nicht enthalten sind, zeigt, wie schwer es den Verfassern des Verbots gefallen ist, Bedeutung und Umfang des Einsatzes von PFAS zu erfassen. Auch die gegenwärtige Konsultation wird wegen der immanenten hohen Komplexität des gewählten Beschränkungsansatzes zu keinen wesentlichen Qualitätsverbesserungen führen.  Der vorliegende Verbotsvorschlag ist wissenschaftlich unausgegoren und wurde auf Grundlage nicht ausreichender Daten entwickelt. Die Datenlage wird auch nach der Konsultation keine belastbare Folgenabschätzung ermöglichen, sozioökonomisch nicht bewertbar und daher angreifbar sein.  Industriepolitisch läuft der Beschränkungsvorschlag den Zielen der EU entgegen. Technologisch führt er zu einer weiteren Schwächung der EU. Die Unsicherheiten bezüglich der Auswirkungen auf die Industrie wird die schon signifikante Abwanderung von Unternehmen aus der EU weiter verstärken und beschleunigen.  Die vorgesehenen Beschränkungen sind in vielen Fällen nicht begründbar und unverhältnismäßig. Wegen der vielen Unzulänglichkeiten, der Vorgehensweise und Konflikten mit bestehenden gesetzlichen Regelungen, ist absehbar, dass das Gesetz durch die Gerichte überprüft werden wird. Das wird die Planungssicherheit der Unternehmen zusätzlich beeinträchtigen und zu einer weiteren Abwanderung insbesondere größerer Unternehmen führen. Viele kleinere, von PFAS abhängige Unternehmen sind in Ihrem Bestand gefährdet, weil sie die benötigten Materialien nicht mehr erhalten und auch nicht ins EU-Ausland ausweichen können.  Der Beschränkungsvorschlag sollte daher von RAC und SEAC nicht unterstützt werden und grundlegend neugefasst werden.  Dr. rer. nat. Günther Bodesheim München, 25.09.2023 |

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| 9519 | Date:  2023/09/25 20:27  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Regional or local authority  Org. name:  Provincie Groningen  Org. country:  Netherlands | General Comments:  The province of Groningen calls for a rapid and total ban of PFAS This contribution reflects the position of the province of Groningen on this consultation. The province of Groningen supports the proposal for a complete ban on PFAS, to protect the environment and the health of our inhabitants. To avoid substitution of one PFAS for another, we support the fact that the restriction proposal targets the entire group of PFAS. Moreover, the province of Groningen believes that it is irresponsible to postpone a ban. Since PFAS are forever chemicals and won’t disappear from our environment, it is undesirable to take 12 years to phase out PFAS. Especially given that the quality of soil, air and water are increasingly under pressure. In Europe, there is increasing attention to a healthy living environment and stricter standards are being set for pollution of soil, air and water through the Soil Health Directive, the Air Quality Directive and the Water Framework Directive. Setting strict environmental standards for PFAS while at the same time letting new PFAS into the environment is counterproductive. A cross border issue Given the impact PFAS are already having on our living environment in combination with the uncertainties that still surround PFAS, the province also sees the importance of a European approach. The PFAS problem is transnational as is clear from the elevated PFAS concentrations in the river Westerschelde, which originate from a factory across the border in Belgium. Since 2020, the Netherlands has been working with Germany, Denmark, Sweden and Norway on a proposal for a European ban on PFAS (Per- and polyfluoroalkyl substances). On February 7th 2023, your agency published a proposal for a ban (restriction) on PFAS. In parallel, a consultation was issued to gather input on this proposal. Why does the province of Groningen support the restriction? One off the tasks of the province, as a regional authority, is to ensure a clean and healthy environment for its residents. PFAS are increasingly known to have harmful effects on the health of humans and animals. PFAS are generally very stable, once in the environment PFAS compounds spread easily through soil, air and water. PFAS are used in countless products, which means that PFAS are present in the environment throughout the Netherlands (for illustration, see references 1, 2 and 3). Research shows that all kinds of (consumer) products and waste streams contain PFAS and that people are exposed to PFAS even in their own homes (4). As a result of this ubiquitous presence humans, animals and the environment are permanently exposed to PFAS with potential risks to human and animal health. Research by the RIVM, the Dutch national institute for health and environment, shows that people in the Netherlands already ingest too much PFAS through food alone (5). People living in close proximity to Chemours (a fluorpolymer plant in Dordrecht) are even advised against eating from their own gardens (6) and at several locations in the Netherlands people are advised against eating self-caught fish (e.g. 7). The drinking water companies in the Netherlands (see the reaction submitted to ECHA by VEWIN) point to the inability to completely remove these substances during the production of drinking water. Lastly, in a few recreational lakes around Dordrecht the province had to give a negative swimming advice due to excessive concentrations of PFAS (8). Social importance Public concern about PFAS is high. This is mainly because the effects of PFAS on humans, animals and the environment are not yet clear. Residents living near a PFAS plant or near PFAS-contaminated land or water are rightly concerned about the effects on their health. Heightened media attention is increasing the public awareness of possible harmful effects and public support for these substances is decreasing. The role of industry To date, several industries are continuing to produce and use PFAS, thus releasing them into the environment. Moreover, PFAS are released not only during the production process, but also during use and at the end of their lifetime. In most waste incinerators PFAS are not completely destroyed, which means that even after phase-out, PFAS will continue to be released into the environment. The province of Groningen is aware that a total ban will demand a lot from the industry, but trusts in the inventiveness of the market to come up with sustainable, safe and circular alternatives. We believe that a rapid and total ban is a good incentive for companies to change their processes. Where exceptions are allowed, the risk assessment of PFAS should be handled more thoroughly. The province of Groningen advocates a stricter burden of proof if companies want to continue using PFAS, as an exemption to the new regulation. A rapid total ban is therefore the only correct course.  References: 1. PFAS concentraties in de Zeeuwse Wateren, Universiteit Utrecht (2022) 2. Landsdekkend beeld van PFAS in Nederlands grondwater, RIVM (2021) 3. PFAS in seaspray, Vrije Universiteit Amsterdam (2022) 4. PFAS in products and waste streams in the Netherlands, Arcadis, 28 mei 2021 5. Risk assessment of exposure to PFAS through food and drinking water in the Netherlands, RIVM, 2023-0011 6. Risicobeoordeling van PFAS in moestuingewassen uit moestuinen in de gemeenten Dordrecht, Papendrecht, Sliedrecht en Molenlanden, RIVM, 2022-0010 7. Consumptie van producten verontreinigd met PFAS uit de Westerschelde, RIVM, 2002-0020 8. Risicoschatting van PFAS in recreatieplas Merwelanden in Dordrecht, RIVM, KU-2023-0013 |

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| 9520 | Date:  2023/09/25 20:29  Content:  Description of analytical methods  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United States of America  Company name confidential:  Yes | General Comments:  Across the globe, climate change is increasingly affecting our lives and the environment. There is an urgent need for system-wide transformation to limit the emission of greenhouse gases. Currently, many polluting hard-to-abate industries such as steel, fertilizer, and refineries rely on chemical processes heavily dependent on fossil fuels. A report of the European Parliament notes that emission-free hydrogen produced by electrolyzers using renewable electricity is key to decarbonizing hard-to-abate sectors like these.  As the hydrogen industry seeks to play a major role in limiting global warming, systemic support is essential to unlock its potential. Currently, there is an absence of alternative technology solutions to materials containing PFAS. These materials are critical to clean hydrogen electrolyzers. A ban on PFAS could significantly affect the growth of clean hydrogen production and delay the decarbonization of key industries.  We strongly recommend -  1. That the ECHA make an exemption for the electrolyzer industry through an exclusion or maximum derogation. This is because of the lack of current alternative technology solutions to PFAS.  2. That the ECHA not place a PFAS restriction on the electrolyzer industry. This is because of the absence of analytical methods to measure PFAS compounds.  3. That the ECHA dedicate resources to develop methods to measure PFAS compounds because of the complications associated with such methods.  4. That the ECHA give the electrolyzer industry maximum time to work on alternative technology solutions to PFAS because development of new technologies takes significant time and effort.  The clean hydrogen industry is being built by people who are very passionate about the environment and sustainable energy resources. Development of new technologies to replace the materials critical to electrolyzer technology, however, could take more than 10 years. A PFAS restriction that affects current technology development could have a significant negative impact and hamper the growth of the clean hydrogen industry.  United Nation’s 2022 Emission Gap Report, https://www.unep.org/resources/emissions-gap-report-2022  European Parliament’s Report on The Potential of Hydrogen for Decarbonizing EU Industries, https://www.europarl.europa.eu/RegData/etudes/STUD/2021/697199/EPRS\_STU(2021)697199\_EN.pdf  BloombergNEF Hydrogen Economy Outlook, https://data.bloomberglp.com/professional/sites/24/BNEF-Hydrogen-Economy-Outlook-Key-Messages-30-Mar-2020.pdf |
| Answer to specific info request 1:  Energy sector |
| Answer to specific info request 10:  The proposed PFAS ban will be unworkable in practice. Suggested limits to measure PFAS compounds are in the parts per billion (ppb) and parts per million (ppm), ranging from 25 ppb to 250 ppm. A March 2023 academic review of current measurement methods and techniques concludes that significant work needs to be done to make a practical field deployable solution for PFAS measurement. Additionally, obtaining clean water samples to test for PFAS compounds will be affected by their presence in ground water. Even if a reliable, field deployable measurement technique existed, and it does not, measuring PFAS compounds in a ground water sample and water used in an electrolyzer will be extremely complicated and considerably resource intensive. Current and emerging analytical techniques for the determination of PFAS in environmental samples Abd Ur Rehman, Michelle Crimi, Silvana Andreescu, Trends in Environmental Analytical Chemistry 37 (2023) e00198 |

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| 9521 | Date:  2023/09/25 20:29  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Fiberflon Teknik Tekstil San. A.S.  Org. country:  Turkey  Attachment:  <redacted>  Privacy statement:  The information/data is submitted confidentially because the protection of commercial interests would otherwise be undermined. The comments include information from our customers/supply chain which has been provided to us in confidence, on the basis of its submission to ECHA for use by EU regulators as part of the ‘universal-PFAS restriction consultation’. | General Comments:  - |
| Answer to specific info request 1:  Please see attached document. |
| Answer to specific info request 5:  Please refer to our previous submission on September 19, 2023 where we provided information on tonnages. We have not repeated this here, as per ECHA’s recommendation. |
| Answer to specific info request 6:  Please see attached document. |
| Answer to specific info request 7:  Please see attached document. |
| Answer to specific info request 8:  Please see attached document. |

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| 9522 | Date:  2023/09/25 20:30  Content:  Information on alternatives  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  ICPP  Org. country:  Germany | General Comments:  - |
| Answer to specific info request 1:  sector: Food contact materials and packaging, packaging for pharmaceutical (pharma packaging), medical devices, cosmetic and hygiene articles sub-uses: paper and board packaging, plastic packaging, other packaging applications Also packaging for dangerous goods which are not included in table 9 |
| Answer to specific info request 3:  We refer to the “Pilot-Scale Fluoropolymer Incineration Study” from Fluoropolymer Group at PlasticsEurope: The study clearly demonstrated that fluoropolymers are converted to inorganic fluorides and carbon dioxide. The inorganic fluorides detected were hydrogen fluoride. A large majority of samples indicated that long-chain PFAS were below levels of 1 ng/m3 (>99% of samples associated with 860°C condition and >98% of samples associated with 1100°C condition). There were no short chain PFAS detected post incineration. TFA was non-detectable in all samples with a reporting limit of 14 µg/m3. The results confirm that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment. The study provides strong evidence that incinerating a mixture of fluoropolymers under representative municipal waste combustion conditions leads to complete mineralization of the C-F bonds, no significant emissions of long-chain PFAS, and no significant emissions of TFA or light fluorocarbons such as CF4 or C2F6. The absence of organic fluorides and more specifically PFAS in tests representative of municipal waste incineration confirms complete mineralization of fluoropolymers. |
| Answer to specific info request 4:  In the plastics industrial packaging industry, very small quantities of polymer processing aids (< 0,1%) based on fluorine-containing monomers are used in polyolefins. These polyolefins will go into the plastic recycling streams with varying PFAS-content. Also some fluorinated packaging or fluorinated gaskets and sealings especially from the croplife sector could end up in the packaging waste stream. Because PFASs are bound in the polymer, they will not be released from the plastic during mechanical recycling to the environment. They remain in the plastic and can be reused in new plastic products. In order to check the TOF-limit of 50ppm (or 50 ppm limit for fluoropolymers) for recycled PE or PP set on the market, a recycler would have to check each recycled batch for PFAS without having the possibility to influence the PFAS concentration during the recycling step. Additionally, currently, there is no standardized analytical method available to check the content of fluoropolymers in plastics, thus the proposed limit for content of fluoropolymers cannot be controlled. Therefore, we ask for an exemption for the output material of the plastic recyclers. |
| Answer to specific info request 5:  We estimate that total emissions to the environment from the contents of fluorinated plastic packaging in Europe are significantly less than 500 grams/year. These estimates are derived from the maximum value of the leach-out studies and the total amount of plant protection products. |
| Answer to specific info request 6:  • Transport packaging (drum, jerrycans and IBCs) for dangerous goods • Technical textiles (Membranes used for the ventilation of IBCs and packagings which must be water, oil and alcohol repellent) • Seals and gaskets for dangerous goods packaging. |
| Answer to specific info request 7:  Plastic regenerate and internal recyclate use pose a major problem in complying with the proposed limit of 50 ppm. Not only the intended use, but also the indirect use via reclaim in types that are actually PFAS-free, but may contain PFAS at significantly lower levels due to internal reclaim. However, this influence decreases over the years due to the potential limitation in the intentional use of PFAS in virgin materials. In order to remain deliverable, we propose a longer transition period for packaging placed on the market (packaging for dangerous goods/sealing/gaskets: 12 years) We would like to add that this suggested time covers also the development time at the packaging producer as well as the implementation at our costumer. The customer/filler must also test their products for the new (PFAS-free) packaging in a time-consuming and costly manner: e.g., pre-storage of the filling materials for several months and subsequent testing of the packaging materials for several months in accordance with dangerous goods legislation. |
| Answer to specific info request 8:  An alternative to fluorination is coextrusion of the primary plastic (typically HDPE) with a thin layer of PA (polyamide) or EVOH (co-polymer of ethylene and vinylalcohol). The barrier properties of coextruded containers are similar as with fluorinated packaging. For the following reasons, these alternatives could only be implemented to a limited extent:- Intermediate container sizes (20-200 L) cannot be produced as CoEx containers. Coextruded packaging could be an extra limitation in the ability to recycle the plastic after use. Fluorinated plastic packagings, on the other hand, can be recycled and possibly used in bottle-to-bottle recycling. In addition to the pure additional costs due to the higher material consumption for the alternative coextruded barrier layer during production, there will also be further additional costs due to the taxes on non-recyclable packaging envisaged in the EU, which would only affect the alternative packaging (multilayer packaging). |
| Answer to specific info request 10:  There are still many open questions about PFAS analysis. We would welcome the development of standardised analytical methods for PFAS in plastics at CEN level. |

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| 9523 | Date:  2023/09/25 20:32  Content:  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  Netherlands  Company name confidential:  Yes  Attachment: | General Comments:  See Non-confidential attachment. |
| Answer to specific info request 4:  As mentioned in the attachment, it is not clear whether the amount of PFAS in paper and board exceeds the maximum concentrations of reach and to what extent. Depending on the scenario however it is likely that it would take several years to phase out the PFAS from the paper and board value chain. The introduction of the PFAS restriction without a transition period would therefor risk the circular character of the paper and board production. Recycled paper may account for more PFAS than allowed under the new value limits and could therefor be discarded as a resource in the production of new paper and board. In the recycling process it is not possible to remove the PFAS that may be present in the collected paper and board. In the collection of paper and board, items containing PFAS such as laminated to-go food packaging material is not accepted. However this is not a guarantee that not a single of such items will be discarded with paper and board. Alternative is to analyse all recovered paper that is to be used in the production process of new paper and board. However since there are no guidelines yet for analysis it is administrative and financially burdensome to analyse all recovered paper and board on PFAS. The introduction of the PFAS restriction without a transition period would have as a possible consequence that no recovered paper is used in the production of new paper and board. For the situation in the Netherlands this would have severe consequences for the circular nature of the paper and board production process: • Only in the Netherlands approximately 2.500.000 tonnes of paper and board is put on the market on a yearly basis. For the production of these materials as much as 87% recycled fibres are used. • In the Netherlands approximately 2.000.000 tonnes of paper and board is recycled every year. |

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| 9524 | Date:  2023/09/25 20:32  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  IPEC Europe asbl  Org. country:  Belgium  Attachment: | General Comments:  - |

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| 9525 | Date:  2023/09/25 20:33  Content:  Environmental emissions  Information on alternatives  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Sensata Technologies Holland BV  Org. country:  Netherlands  Attachment:  <redacted> | General Comments:  Sensata understands the proposal of 12 year derogation for electronic devices (in sector transport and HVACR) that ensure safety of operators, persons or goods to bring to the market for new systems. High socio-economic costs to customers will be present due to the unavailability of electronic devices without fluoropolymers or redesign of HVACR systems. Sensata believe that the 12 year derogation should not be applicable for aftermarket replacement parts, in which Sensata requires a grace-period of 15 years beyond the derogation period which is typical for project nomination contract. Similar statement was made in submission 4471 and 6365. |
| Answer to specific info request 1:  a. vast amount of Sensata devices can be categorized as “electronics in transport” sub-use. Sensata is market leader in many Aero/Heavy Vehicle and of Road (HVOR) /Automotive electronic sensors, electrical protection devices (automotive and industrial) b. Some specific electronic devices are part of the HVACR sector/sub-use. |
| Answer to specific info request 5:  a. ~300M elastomers are purchased annually (each 0.23gram estimated based on most common sizes with 50% PFAS content) results in 35tonnes per year which is negligible with respect to table 11 transport sector. b. Its emissions are considered negligible with respect to table 11 transport sector. Emissions of the production at the polymer supplier is considered as small according to our suppliers Solvay 6179, Chemours etc., non-existing emissions during lifetime use and main emissions at end of life. Sensata assumes that devices are recycled for valuable components and its fluoropolymers to be incinerated to recover energy or landfilled, though Sensata and its customers have no visibility on the waste stream. Specific Sensata HVACR device do not contain PFAS components, these devices are part of the system using F-gasses and are designed for minimizing the leakage. |
| Answer to specific info request 7:  a. Tonnage listed above b. The key functionalities provided by PFAS fluoropolymer coatings and seals are to protect the electronics in Area/HVOR/automotive conditions. Especially, a harsh environment in contact with exhaust gases requires adhesives and coating materials against the exhaust media where PFAS fluoropolymers are stable and robust but non-PFAS polymers are not. [Modified by Jun Bae on Sep 18] Partly as humidity repellent material, vast majority to ensure leak tightness against aggressive hydrocarbon-based media in automotive/HVOR/industrial conditions. Ever more demanding conditions, like mandatory additions of bio-fuels, resulted in further exclusions of non-PFAS elastomers. Wires and Plastics. Fluoropolymers are commonly used in wires and cables as they are highly temperature resistant, corrosion resistant, waterproof, and oil-resistant, low dielectric constant (excellent electrical insulator properties), flexibility, high stress crack resistance, UV resistance, long life, etc. These therefore can be used in harsh environments and places such as automobiles and are playing important role in the products for exhaust gazes monitoring and control. Fluorotechnology products are critical for today’s safe and fuel-efficient automobiles, trucks and buses, that rely on their unique, high-performance properties. From engines and brakes to fuel components and electronics, most modern automotive systems rely on Fluorotechnology’s durability and resistance to heat, chemicals and abrasion and vapor-barrier characteristics. c. Industry sector: Sensata is a key player in automotive, aero, industrial and HVOR applications by providing essential (HVACR) pressure sensors / switches, temperature sensors, magnetic position sensors, exhaust pressure and temperature sensor, electrical protection and many more, see Sensata.com. Sensata is in many of these markets a significant supplier among suppliers as Denso, Continental, Bosch, Delphi etc. All are using similar technologies and are similar dependent on the benefits of fluoropolymers [Kramer to confirm if we can add the competitors]. d. Sensata market share is dominant Globally for some applications. e. Alternative not yet available: Limited alternatives exist, see in appendix table 8, Other fluoroelastomers substitutions are technically feasible, economically undesired otherwise Sensata would have implemented this in the competitive environment. The alternatives safety hazard is compromised, and most are expected to have significant loss of application reliability due wear or even infant-mortality, similar as stated by OEMs summarized in 6261 and 6365. a. Cost effective alternatives of one of the application oil immersion cooling can be AEM, though these would swell significantly and consequently would lose its strength and elastomeric properties 6268. AEM which as of today already having supply shortage till 2028 and is expected only to cover a small portion of fluoropolymer market in the foreseen derogation period. Alternatives for HVACR devices are in development and would the equipment, process and end-users cost when transition from F-gasses media to CO2 with safety risk of emissions and even leakage in small compartments like automotive cabins leading to drowsiness or worse. Other F-gas free refrigerants can be used in derivative designs, these are more flammable with its obvious safety risks. Additional measures needs to be taken to overcome these risks and will drive cost of HVACR systems. b. existing polymers (silicones, polyurethanes) tubes/seals could not be used for e.g. fuel hoses for safety reasons (flammability, chemical resistance…), the most immediate alternative to fluoropolymers in fuel hoses would be metal, which were the historical technical solution. Metallic tubes would mean heavier assembly and would increase the fuel consumption. c. Feasible substitutions: Alternatives covering the full range of applications of PFASs in these applications for the transport sector are not yet on the market. Use of alternatives would require testing, certification and in some, perhaps many, cases re-design of equipment at Sensata and all of Sensata customers e.g. all from ACEA. Similar is applicable for re-designing HVACR systems. R&D of ~$7M/y euros in the next 12.5 years are needed to re-design the current >~3000 devices [1500 APT, 1500 additional] containing >300M PFAS elastomers components or devices used in HVACR systems. This will be on cost of the focus of electrification transition. Each feasible alternative will have on average significant reduction of reliability, reduced lifetime and safety risk for all applications e.g. passenger cars. The alternatives a more difficult to manufacture, lower yields, higher in component costs, typically heavier in weight and therefore a CO2 penalty from cradle-to-grave. What is not clear and, if so, how an extension of the existing exemptions (derogation) can be applied for in case no substitutions are found. Sensata would like to have the possibility to provide every year updated arguments to review the agreed derogation periods. g. No-alternatives: The safety will be compromised for e.g. devices in the fuel system, see table in power point/appendix similar statement is shared in 6261. In the last decades OEMs optimize fuel efficient systems with sensors that combine pressure and temperature into 1 device. No PFAS free alternative exist of such combined device. Only solution results in split of device functionality at system level. Such is technical feasible in 12.5 year in corporation with the OEMs with a surplus of producers and customer cost besides the CO2 penalty for making extra devices and weight of the vehicle. The cables produced using fluoropolymers often have superior physical, mechanical and electrical properties, the highest resistance to burning and the lowest smoke generation potential. These properties are inherent in most fluoropolymers and are obtained without the introduction of additives and plasticizers that may leach out over time and reduce wire performance. The replacement of some PVC applications with non-halogen cables makes sense in applications where some loss in flame and smoke properties are acceptable in comparison to a specific need as required in the automotive. It should be pointed out that non-halogen cables, or better described as “non-chloropolymer” cables, have lower physical properties, lower flame resistance, and higher smoke generation than fluoropolymer cables. Combined with performance characteristics such as insulation resistance, chemical resistance, fire performance, cut through resistance, abrasion resistance, etc., it is obvious that that fluoropolymers must be considered for use when performance and safety are the primary goals. Our supplier’s feedback is that no alternatives for PTFE or in general for fluoropolymers on the market. Some suppliers try to develop a PTFE without PFAS, but there is a need to have more time to secure alternative technologies and appropriate alternative substances. |

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| 9526 | Date:  2023/09/25 20:37  Content:  Scope or restriction option analysis  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Essar Oil UK Limited  Org. country:  United Kingdom | General Comments:  The restriction proposal baseline study for Petroleum and Mining sector, which focused on the use of PFAS substances in exploration, exploitation and offshore processing of oil, has not taken into consideration the use of PFAS substances in the onward processing of oil (petroleum refining) or refinery product distribution chains e.g. distribution of automotive fuels. Refining operations are controlled chemical reactions which occur at high temperatures and / or pressures, often in the presence of a catalyst (which can be corrosive e.g. hydrofluoric acid) and may generate corrosive products which require onward reaction / transformation by secondary processes. These refining activities are not present in the upstream activities of petroleum and mining. Refinery chemical reactions do not directly use or manufacture PFAS substances. However PFAS is present within industrial equipment, mostly in a solid form [e.g. PFAS components of dynamic and static seals, pump membranes/ diaphragms, PTFE linings in pipes and PTFE-coated bolts] or gaseous form [e.g. refrigerants]. This PFAS poses a low risk of exposure to the environment during operations. Additionally, PFAS substances are used by manufacturers in the creation of raw materials which are then use in manufacture of process unit equipment such as seals, bushes and some electrical parts. Whilst these refining components do not themselves contain PFAS, the upstream manufacturing process for the raw material does. At present, information from a number of raw material manufacturers suggests that a viable alternative to PFAS is not likely to be available within the next 5 years. The refinery supply chain is vast with many raw material and feedstock suppliers producing materials that do not contain PFAS, but where manufacturing processes utilise PFAS-containing substances in equipment designed for use at high temperatures and / or pressures and / or corrosive environments. A risk-based approach to restriction of PFAS is required especially for industrial applications where alternatives have not been developed. |
| Answer to specific info request 1:  The restriction proposal baseline study for Petroleum and Mining sector, which focused on the use of PFAS substances in exploration, exploitation and offshore processing of oil, has not taken into consideration the use of PFAS substances in the onward processing of oil (petroleum refining) or refinery product distribution chains e.g. distribution of automotive fuels. As a consequence, refinery operations (conditions and applications) are not exhaustively covered under the sector identified. Petroleum refining transforms crude oil and other feedstocks (e.g. vegetable oils, pyrolysed waste plastics, used cooking oil, animal fats) and into fuels, petroleum intermediates and chemicals for use in industry and consumer sectors. Refining operations are controlled chemical reactions which occur at high temperatures and / or pressures, often in the presence of a catalyst (some catalysts are corrosive e.g. hydrofluoric acid) and can generate corrosive products which require onward reaction / transformation by secondary processes. These refining activities are not present or represented in the upstream activities of petroleum and mining sector. Due to the complex nature of distinct refinery and secondary processes, each carried out within purpose designed equipment or process units, refining operations and refinery products distribution has multiple critical applications which contain PFAS substances or raw materials manufactured from PFAS precursors e.g. loading arm swivels, through to valves, gaskets, pump diaphragms etc. |
| Answer to specific info request 2:  PFAS solids are not expected to breakdown during operations. During the operational phase, the risk of release would be due to product degradation over time from mechanical stress, erosion, chemical reaction. This could lead to the release of PFAS into product streams or leaching into secondary processing units. During the disposal stage, potential release of particles into the atmosphere would occur if incineration is below recommended temperatures. PFAS gases (used for refrigeration) could be released to the atmosphere during the operational phase due to leaks in the equipment. Disposal of PFAS gases is in line with national disposal requirements and undertaken by a licensed disposal specialist. |
| Answer to specific info request 5:  The derogation proposed for fluoropolymer applications in petroleum and mining industry (until 13.5 years after EiF) does not apply to the refining operations and fuel distribution sector. |
| Answer to specific info request 6:  To date, the inventory of PFAS within refinery and fuel / chemical distribution equipment has determined that PFAS substances are present in gaskets and sealings, loading swivel arms, pumps/ compressors, pump diaphragms, PFAS-coated bolts and refrigerants. These core pieces of equipment are widespread around the various refinery processing units and distribution terminals. From experience, supplier information regarding these pieces of equipment primarily focuses on performance of equipment rather than on composition, meaning that percentage of PFAS present in these components is not often known. As yet, there are no known viable alternatives for these PFAS-containing equipment. The types of PFAS identified are mainly fluoropolymers such as PTFE, FKM and FFKM but this does not mean that other types of PFAS are not present. One supplier highlighted that a seals manufacturer had no alternative product to replace the current PFAS-derived raw material and that an alternative was not likely to be available in the next five years. An exemption for all PFAS applications in refineries and fuels / chemical distribution within the industrial sector is requested, until proven replacement technology is available for each and every application. |
| Answer to specific info request 8:  Please see statement 6. |

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| 9527 | Date:  2023/09/25 20:39  Content:  Scope or restriction option analysis  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 Garden Machinery Federation (EGMF)  Org. country:  Belgium  Attachment: | General Comments:  EGMF is the European federation representing major garden, landscaping, forestry, and turf equipment manufacturers. Through its 30 European corporate members and 7 National Associations, EGMF represents about 23 million units placed on the European market in 2021, accounting for around 80% of garden machinery, and EGMF members employ over 120,000 people in the EU.  We welcome the opportunity to comment on the Restriction Proposal of Per- and Polyfluoroalkyl substances (PFAS) submitted by the competent authorities for REACH of the Netherlands, Germany, Denmark, Sweden, and Norway which aim to reduce PFAS emissions into the environment and make products and processes safer for people.  The group of PFAS is not a single substance, but a class of substances containing many thousands of individual chemicals. Not all PFAS are classified as “hazardous” under the CLP Regulation, especially the polymers that we use in our equipment. A general restriction based only on the persistence of PFAS would thus contradict the risk-based approach.  PFAS are used for various applications in the garden and outdoor power equipment, such as fuel hoses, injectors, manifolds, gaskets, and fan wheels. Until appropriate substitutes are found, these substances remain critical to guarantee the durability and safety of our equipment.  Having considered the extensive use of PFAS in our members' products, EGMF makes the following requests in respect of the PFAS restriction proposal: A further assessment is made on the impact of the proposed restriction on specific types of machinery; Exemptions are granted for fluorinated polymers that are essential and used for various applications in garden and outdoor power equipment; Exemptions are granted for applications and equipment where no appropriate substitute is available, including outdoor power equipment, as well as for spare parts to ensure that products could be repaired and reused and to provide safety products to consumers; Sufficient time is provided to develop and test alternative substances, as other substances do not offer similar properties in similar extreme climate conditions, thus not ensuring the necessary safety and durability of the equipment.  EGMF also wishes to stress that, in the limited time that was available during this consultation, our members have struggled to obtain the necessary information from their supply base that was needed in order to provide comprehensive answers to the specific questions posed in the questionnaire. We have therefore submitted a position paper rather than attempt to answer the individual questions. We trust that this will be accepted and the points made in the position paper are taken into account during the consultation. |
| Answer to specific info request 1:  Please see the EGMF position paper, attached to this consultation response. |
| Answer to specific info request 5:  Please see the EGMF position paper, attached to this consultation response. |
| Answer to specific info request 6:  Please see the EGMF position paper, attached to this consultation response. |
| Answer to specific info request 7:  Please see the EGMF position paper, attached to this consultation response. |
| Answer to specific info request 8:  Please see the EGMF position paper, attached to this consultation response. |

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| 9528 | Date:  2023/09/25 20:39  Content:  Scope or restriction option analysis  Baseline  Description of analytical methods  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Vertiv srl  Org. country:  Italy | General Comments:  - |
| Answer to specific info request 1:  Following the divisions of Annex XV restriction report, our products can fall into the following Sector and Sub use. Sector: Applications of fluorinated gases (Annex E.2.8.) Sub-uses: Refrigeration Air conditioning and heat pumps In between the defined Sectors and sub-uses, we can more precisely define our application as the Information Technology Cooling Equipment, covering both air coolers and liquid coolers dedicated to the data center conditions management. They are a specific product with dedicated features. The first characteristics are reliability and efficiency. Reliability because they need to run 24/7, independently of internal load charge and external conditions, and any lack in functionality is driving to a not conceivable economical loss. Efficiency because we are talking about huge quantity of energy involved in Data Center, so the efficiency is playing an important economical role. Our catalogue is quite wide, and it comprises air cooling unit from few to some hundreds of kW of cooling capacity, to be located indoor or outdoor the Data Center. We have AHU, with and without evaporative effect always dedicated to DC and finally liquid chillers, up to two Megawatts. Refrigerants used are HFC and HFO. |
| Answer to specific info request 5:  Our ITC Equipment application does not seem covered by any current derogation. |
| Answer to specific info request 6:  About the consumption of refrigerant in the Vertiv European area for the year 2022, including liquid chillers and air-cooling machines for IT cooling purposes. The majority is used in manufacturing, with a small portion for Central Service. It should be noted that we have also used some quantities locally, and others have been used by third parties for installation and commissioning of air-cooled units sold without refrigerant, which are filled on-site. In total some hundreds of tons of refrigerants, difficult to better estimate. Additionally, PFAS are confirmed to be used in a significant number of components within our machines. The following is a non-exhaustive list: • Cabinet vent / filter (confirmed) • Coax cables (confirmed) • Coolant for liquid cooled servers (confirmed) • Electronics – diodes, capacitors, etc. (confirmed) • Exterior cabinet paints and coatings (confirmed) • Heat Exchanger tubes – hydrophobic coating (potential) • High Temperature and/or chemically resistant O-rings / Seals / Gaskets (confirmed) • Lithium-Ion Batteries – electrode substrate and in the electrolyte (confirmed) • Plumber's tape (PTFE / Teflon) (confirmed) • Printed Circuit Board Coatings (potential and likely) • Pumps (using PFAS o-rings, seals, gaskets) (confirmed) • Semiconductors (confirmed) • Wire coatings and insulation (confirmed) Moreover, many of our suppliers also use PFAS in their processes. Examples include cleaning tools, degreasing stamped metal dies, plastic and rubber mold release agents, and electronic manufacturing atmosphere purges. Therefore, understanding PFAS risk can be divided between intentionally added PFAS used to achieve desired product performance and residual PFAS remaining from various processes. PTFE (Polytetrafluoroethylene)/Teflon plumber's tape, which we expect to be used on any threaded connection for a gas or liquid system, serves as an example of intentionally added/used PFAS. An example of residual PFAS is PFOA (Perfluorooctanoic acid), which is used in the manufacture of almost all semiconductors. Containment measures currently in place or upcoming We are currently following the current F-Gas Regulation and have implemented all the required measures to detect any refrigerant leakage. Furthermore, our devices are generally equipped with sensors and controls that detect any adverse effects resulting from an initial leak of refrigerant. Total estimated turnover linked to PFAS related substances, IT cooling equipment Considering only the market with Dx Circuit (referring to the impact of the refrigerant only, excluding residual components with PFAS) in EMEA for the year 2022: • Estimated DX market for IT cooling devices in EMEA: 669 million EUR However, if we consider the impact of other components with PFAS, we need to include all Datacenter EMEA Thermal sales: • Estimated total market for IT cooling devices in EMEA for the year 2022: 989 million EUR Impact on the product availability in case of ban There is no immediate alternative in the event of a ban. Currently, most customers are not accepting refrigerants that are mildly flammable, which also rules out the use of R32. So, if the HFO refrigerants should be considered subject of ban, we ask at least for a timely based derogation for the IT cooling Equipment. To have time to build a solution (efficient, reliable, non-flammable and economical as required) in the Industry, which is currently not available and is far from being seen. |
| Answer to specific info request 10:  In the Annex E there is a small reference to Datacenter Cooling Devices, i.e. : E.2.8.2. Alternatives E.2.8.2.1. General consideration of the availability of alternatives Alternatives need to be identified at the specific application level. … E.2.8.2.2. HVACR applications … Domestic refrigeration … Electronics cooling, heat exchanger part with fluorinated gases or other refrigerants Large, isolated data centres may be able to use alternative refrigerants such as ammonia without problems for cooling. Small systems may be cooled using basic ventilation or small-scale AC systems for which hydrocarbon charge size would not be problematic. Water is also an alternative refrigerant for the safe and efficient cooling of data centres… This analysis seems to us absolutely not realistic. The largest numbers of IT Cooling Equipment are not using and not willing to use ammonia for safety reason. And there is not so small-scale AC system, for internal use, where hydrocarbon can be used. Therefore, HFO and HFO mixtures are currently the only usable refrigerants with a low GWP and cannot be replaced now with efficient, reliable and economical alternative solutions as required. |

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| 9529 | Date:  2023/09/25 20:45  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Italy  Company name confidential:  Yes  Attachment: | General Comments:  See attachment |
| Answer to specific info request 1:  See attachment |
| Answer to specific info request 2:  See attachment |
| Answer to specific info request 3:  See attachment |
| Answer to specific info request 4:  See attachment |
| Answer to specific info request 5:  See attachment |
| Answer to specific info request 6:  See attachment |
| Answer to specific info request 7:  See attachment |
| Answer to specific info request 8:  See attachment |

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| 9530 | Date:  2023/09/25 20:47  Content:  Hazard or exposure  Description of analytical methods  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Infineon Technologies Dresden GmbH & Co. KG  Org. country:  Germany | General Comments:  We made an initial input to this consultation in 13th June 2023. The associated reference number is bb3ca7a6-d243-4b52-b57d-f40c1087d9e7 |
| Answer to specific info request 1:  Semiconductor products are the key enabler for improved energy consumption and performance across a wide range, of everyday technology applications in society. The semiconductor sector depends on various application of materials (gases, solids, liquids) falling in scope of the PFAS definition. Thus, our following comments are related to the uses and sub uses identified in Table 9 in the Annex XV restriction report. Use sector: Electronics and semiconductor (Annex E.2.11.) Sub uses: Semiconductors / Wires and cables / Coating, solvents and cleaning / Electronic components / Heat transfer fluids / Advanced semiconductor packaging / Photolithography Use sector: Applications of fluorinated gases (Annex E.2.8.) Sub-uses: Refrigeration / Insulating gas in electrical equipment |
| Answer to specific info request 2:  Some of our sensor chips may contain PFAS to provide a safe connection to the environment while still protecting the sensor. In Europe laws were enacted in the past to characterize the recycling of semiconductor products to achieve minimum environmental impact. For Example: the WEEE Directive (European Parliament and Council, 2012) for consumer electronics and the ELV Directive (European Parliament and Council, 2000) for vehicles. End-of-life phase of equipment and articles in semiconductor manufacturing: According to a 2023 ESIA publication, the end-of-life of semiconductor manufacturing sites is estimated to be more than 25 years. The crucial need for clean room manufacturing and the use of special hazardous chemicals in high puritiy quality mean that for some use cases only fluoropolymers can fulfill the requirements. This is the reason why a production site may contain several tons of fluoropolymers in pipe linings, valves, seals such as O-rings, etc. (Source: PFAS Consortium - Articles Working Group, 2023). Due to the persistence of fluoropolymers and the long-term use of semiconductor equipment, the emissions in the end-of-life phase of the PFAS-containing equipment are low compared to the quantities found in a fab. Any waste generated is collected according to the harmonized European waste code numbers for mixed plastics (European Commission, 2002) and sent for proper disposal. |
| Answer to specific info request 3:  During production: The use of PFC gases (perfluorinated compounds), some of which are considered PFAS as defined in the Restriction Report, is still essential for semiconductor manufacturing. During these thermally highly demanding processes or also during chamber cleaning, a certain amount of the gases is already converted in the process and decomposed there into less harmful components (https://www.ipcc-nggip.iges.or.jp/public/2019rf/pdf/3\_Volume3/19R\_V3\_Ch06\_Electronics.pdf, see Table 6.11 there). In order to further reduce the remaining PFC emissions, the semiconductor industry has agreed ambitious targets for many years. For example, abatement tools have been installed on a voluntary basis. These abatement tools usually work with a destruction removal efficiency (DRE) that depends on the PFC used. For example, the PFAS C2F6 has a standard DRE of 0.95 according to Table 6.17 (https://www.ipcc-nggip.iges.or.jp/public/2019rf/pdf/3\_Volume3/19R\_V3\_Ch06\_Electronics.pdf). In these abatement tools, the remaining PFC gases are further reduced using high temperatures (e.g., natural gas burners or electric plasma systems) by first destroying the PFC gases in a combined burner/scrubber system through the chemical reaction of combustion, and then scrubbing and neutralizing them through subsequent washing processes. By applying these technologies, PFC emissions to the environment could be impressively reduced over the years. Waste treatment: The frequently expressed thesis that PFAS are indestructible is incorrect and has been impressively proven wrong by a number of research results. PFAS can be very well degraded by incineration or pyrolysis. Conventional waste incinerators usually cover a temperature range of 600-1600 °C (https://www.sciencedirect.com/science/article/pii/S2095809917300796). At least 1,100 °C for 2 seconds results in complete decomposition of most PFAS (Yamada T. et al. 2005) (https://www.sciencedirect.com/science/article/abs/pii/S004565350500425X). Even under state-of-the-art domestic waste incineration conditions, PFAS are converted to inorganic fluoride at a minimum incineration temperature of 850°C (Aleksandrov K. et al. 2019). Investigation of incineration of PFAS substances PFOA, PFHxA, PFOS, recognized as problematic and therefore already regulated, at different temperatures (800 °C, 900 °C, 1000 °C) showed that at higher temperatures of 1000 °C no formation of fluorinated by-products occurred (Residual organic fluorinated compounds from thermal treatment of PFOA, PFHxA and PFOS adsorbed on granular activated carbon (GAC) | https://link.springer.com/article/10.1007/s10163-016-0532-x). |
| Answer to specific info request 5:  The European Commission recently adopted a series of proposals aimed at, among other things, shaping EU climate, energy and transport policies to reduce net greenhouse gas emissions by at least 55% by 2030 compared to 1990 levels. To achieve this goal, it is essential not only to maintain microtechnology in Europe, but to increase it strongly. The Chips Act of the European Union aims to reach this goal. It recognizes the importance of semiconductors and their manufacturing to achieve the above-mentioned goals. For this purpose, the German Infineon Technology AG has Frontend and Backend production sites in Regensburg and Warstein and R&D in Neubiberg near Munich. Within our group we also have production sites in various European countries: Dresden (Germany), Villach (Austria) and Cegled (Hungary). Semiconductors from Infineon Technology AG help to generate electricity from renewable energy sources. They also offer increased efficiency at all stages of the value chain in the energy sector: in generation, transmission, storage, and in particular, in the use of electricity. They form the basis for the intelligent and efficient use of energy: in industrial applications, power supplies for computers and consumer electronics, as well as in motor vehicles. Semiconductor manufacturing is characterized above all by the fact that it mostly takes place under clean room conditions and in closed systems. Any entry of impurities into our productions usually has a devastating effect on the quality of our products and is avoided wherever possible. Due to that the presence of employees in the clean room is reduced to the minimum. Under normal production conditions, there are no measurable emissions at the workplaces. In general, the semiconductor manufacturing can be divided into two parts - "Frontend" and "Backend". In the Frontend, the raw wafer of silicon is processed, while in the Backend, the finished products are manufactured from the separated chip (circuits). In the Frontend, PFAS are essential in the following areas: Photolithography and Plasma Etching. Photolithography: Photolithography is one of the central processes for manufacturing integrated circuits. It involves using an exposure process to transfer the image of a photomask onto a photosensitive photoresist. Subsequently, the exposed areas of the photoresist are dissolved (alternatively, dissolution of the unexposed areas is also possible when the photoresist is cured under light). This creates a lithographic mask that allows further processing by chemical and physical processes, ultimately leading to the microchip integrated circuits. Photoresists and anti-reflective coatings for specific applications also contain mostly PFAS, as their chemical and physical properties (wetting agent and photoactive, combined with chemically inert behavior) are necessary in the exposure process of lithography to achieve the desired process result. Especially the generation of more advanced products with smaller and smaller structures require PFAS. These are, for example, photoacid generators (PAGs, such as sulfonium and iodonium acid salts with fluorinated anions), which are essential components of the chemically amplified resists (CARs) used today. When exposed to ultraviolet (UV) light, they generate so-called superacids, which cause the solubility change of the photoresist. All proven successful PAGs are fluorinated. The PAG content in the CAR is small (order of magnitude 1%, mostly smaller). Due to process control (spin coating, development, stripping or ashing), the main part of PFAS is destroyed or ends up in the solvent waste, which is properly disposed of. Only a very small proportion is ultimately found in wastewater. Top anti-reflective coatings (TARCs) require a very low refractive index, minimal surface energy and excellent barrier properties. All these properties are achieved by using fluorinated copolymers based on styrene, acrylate and methacrylate. At present, there are no suitable substances that can provide all the above-mentioned properties. If they can be developed at all in the future, their possible use in production will certainly take decades, since a large number of parameters will have to be optimized. Plasma etching: Plasma etching is a material-removing, plasma-assisted dry etching process in which a high-frequency or electrodeless microwave discharge is ignited in a vacuum reactor filled with an etching gas (often low-molecular-weight PFAS), thus generating a highly reactive, etch-active plasma. The resulting plasma reacts with the wafer surface and cleans it or creates structures that have been prepared in previous steps (e.g. lithography). The main criterion for the selection of the etch gas is its ability to form a highly volatile reaction product with the silicon-based wafer surface (silicon or silicon dioxide). Therefore, etching gases that ideally contain fluorine (PFAS like carbon tetrafluoride and octafluorocyclobutane) are generally used when etching structures. Since the chemical reactivity between fluorine and silicon is very high, the reaction product of the etching reaction is volatile silicon tetrafluoride, which has a high vapor pressure. These reactions can be controlled very well, while other etching gases (e.g. chlorine-containing etching gases) also give volatile silicon tetrachloride, but either react much more uncontrollably or less selectively, thus making it very difficult or in some cases impossible to generate the necessary fine structures on the wafers. Thus, the gaseous PFASs used are extremely difficult to substitute. By far the largest proportion of the PFAS gases used either already react in the plasma chamber or are systematically burned off in the downstream abatement process. This means that only a small proportion of PFASs is emitted via the exhaust air. PFAS-containing materials are also used in the Backend, which cannot be easily replaced here either. Adhesives: PFAS can also be a component of semiconductor products, e.g. in some electrically insulating adhesives, 70-90 wt% filler content of the PFAS Polytetrafluorethylene (PTFE) may be present to reduce stresses. This filler also prevents moisture absorption, which also leads to the prevention of corrosion within the semiconductor product. The PFAS remains in the product and does not change throughout the service life. At end-of-life, the semiconductor product is sent normally for proper disposal. Therefore, no emissions are observed. PFAS-containing materials are also used in production equipment because PFAS-containing polymers have unique properties that are mostly not replaceable by other materials. Equipment: In our production, highly aggressive media (e.g. hydrofluoric acid, alkalis) have to be handled in some cases, or also highly pure media (such as ultrapure water). This requires the use of fluorinated polymers in our production equipment throughout the entire production process. Thus, many valves, seals and pipe linings are affected. Replacing all these materials would be a major challenge, since mainly the respective equipment manufacturers have the knowledge about the composition of the individual components / tools. The supply of spare parts could also become a problem. Although there is one of the most important equipment manufacturers, ASML in the Netherlands, many manufacturers are located outside the EU. The use of materials containing PFAS is very widespread, but we have no knowledge of any emissions via wastewater. In the case of equipment disposal, this is done by a certified disposal contractor. There are no other known emission paths. A special case of semiconductor manufacturing is the production of power semiconductors. Infineon operates such a production site in Warstein. Power semiconductor chips are not intended for consumer use and require embedding in a controllable electrical structure - a power module. In these power modules, several semiconductor chips are mounted on boards and wired to control elements, which enables the conversion of current. Therefore, power modules represent an essential core in electric cars, charging stations, electric trains, wind turbines and solar farms; crucial elements for the green electrification of the EU. Embedding power semiconductors in power modules that control thousands of volts requires sophisticated PFAS-based assembly techniques to produce safe and durable products. PFAS-related processes for power module assembly include the following: 1. Paste soldering relies on a partially organic paste. It requires thorough cleaning with the PFAS hydrogen fluoride ether (HFE) to remove paste residues that would prevent further assembly steps and fatally damage the sensitive semiconductor during operation. Reliable and complete removal is not possible with alternative cleaning methods. Previous developments to avoid this undesirable and costly cleaning step have not been successful. The failed attempts to establish alternatives to date indicate that a long transition period is required to find alternative methods. 2. In another application, PFASs are used as adhesion promoters to fix subcomponents of power modules before the next permanent assembly steps. Absolute residue-free evaporation of these adhesion promoters at elevated temperatures is critical and can only be guaranteed with chemically inert and non-adhesive PFASs without risk of ignition. 3. The assembly of power modules involves pressure-dependent processes. Whenever materials are permanently pressed together, a non-adhesive PFAS film is required as a demolding aid to allow removal of the components from the press cavity. 4. In another application, the use of PFAS in the manufacture of power modules is attributed to the electrically insulating and non-flammable properties of PFAS. To safely handle current up to 10000 V, defect-free module components are required. Only an initial test under these conditions in an insulating PFAS environmental bath enables a test that can function safely. To date, only chemically inert PFAS can be removed without leaving residues, allowing further assembly of the test components, and an insulating environment allows testing of these voltage classes without fear of ignition. |
| Answer to specific info request 7:  A lot of different PFAS (gases, solids, liquids) are used in many applications in the semiconductor manufacturing process. Semiconductor manufacturing is a highly complex process and production times vary depending on the complexity of the products, but on average it can take several years from research and development to the final product. The complexity of the products requires a smooth and coordinated workflow between the individual processes, whereby the materials used also work together and depend on each other, as is the case also with PFAS. The proven uniqueness of PFAS combined with the proposal to restrict or ban the entire group of substances in the EU would lead to an extremely large and unprecedented challenge for adequate substitution in terms of the required technical performance and the environmental and human health impacts ("Regrettable Substitution"). A majority of PFAS cannot be replaced by alternatives according to current knowledge even in long term and it will be extremely difficult, to find chemical substances which are suitable and equivalent to PFAS in terms of their unique properties and which have no unknown or unforeseen hazards. Thus, for many applications, it requires a great deal of effort and investment in basic research and development to find PFAS-free alternatives. Once a PFAS-free alternative exists and is available, this needs to be implemented and qualified within the associated processes. This process must be carried out again for each possible alternative, this requires both time and may lead to necessary changes (e.g. design requirements and properties of the product, manufacturing process and -equipment). Therefore, a temporary exemption from the restriction only makes sense if alternatives are available and this is more than doubtful even after the expiry of the proposed 13.5 years. For example, in photolithography, one of the major process steps, the potential timeframe for substitution is 15 to 20 years or more. The substitution time to be estimated depends heavily on the application of PFAS and whether a PFAS-free alternative can be found and made available at short notice by global formulators and their upstream chemical suppliers. Without an appropriate exemption, there is a risk that the proposed full restriction of PFAS will worsen the supply of the semiconductor industry with production materials required during semiconductor manufacturing or that these materials will no longer be available. An appropriate exemption should be granted for the semiconductor manufacturing process, covering the entire semiconductor manufacturing ecosystem and including upstream and downstream supply and value chains. This should not only include the materials and precursors to manufacture the semiconductors. It must also be possible for the customers and users of the semiconductors to incorporate the semiconductors in turn into their products and thus to use the semiconductors over the longer term. Furthermore, the production equipment must not be forgotten, where e.g. also the spare parts supply must be possible in the future, as well as the devices which are necessary for R&D activities like e.g. evaluation boards. Semiconductor manufacturing in Europe without the use of PFAS is therefore currently not possible. A general restriction of PFAS without an appropriate exemption would have very negative effects and consequences for European semiconductor companies as well as their suppliers and customers. A general PFAS ban could have serious negative consequences for the entire industrial manufacturing landscape in Europe. A few months ago, the comparatively harmless shortage in the supply of semiconductors had a serious impact on e.g. the automotive industry, leading to major production reductions and stops. Future investments in Europe depends on legal certainty and the existence of stable supply chains and skilled workers. Infineon commits to Europe as an important business location and thus, e.g. operates a large part of its front-end manufacturing there, where Infineon recently announced plans to expand semiconductor production at its Dresden site with the largest single investment of €5 billion in the company's history. A restriction on PFAS would have a direct negative impact on our revenue (FY 2022: €3.4 billion in Europe and €14.2 billion worldwide) and employees (FY 2022: 21,703 in Europe and 54,286 worldwide), as production with PFAS is not possible in Europe. The majority of Frontend sites are located in Europe, while the majority of Backend sites are located in Asia. Since the Frontend sites are the suppliers of the Backend sites, if the Frontends stop production, the Backends would also have to stop production after a short period of time because they would run out of raw materials for their production. A general prohibition of PFAS for the semiconductor industry, its suppliers and customers must be avoided under all circumstances to eliminate a locational disadvantage for Europe. |
| Answer to specific info request 10:  There is currently no analytical methodology that would be applicable to all individual PFAS compounds as defined by the OECD and provide satisfactory results. There are too many different PFAS compounds for this. In the meantime, some analytical methods have been tested that can detect a few PFAS species in semiconductor manufacturing wastewater. However, this analysis by liquid chromatography together with tandem mass spectrometry (LC-MS/MS) quickly reaches its limits, since comparative standards are only available for a few substances used. Again, it has not been possible to find an analytical method that can detect all PFAS in a comprehensive manner. Therefore, it is very important to conduct extensive research to find and improve suitable analytical methods so that the semiconductor industry is able to provide analytical evidence that it can comply with the limits (e.g., US EPA 537.1 (modified)). Currently established is the determination of total fluorine in the sample. However, the detection limit here is 50 ppm. This is a value far above all limits (ppb, i.e. one one-thousandth below) that apply to PFAS. The proportion of inorganic fluorine can also be determined with the same accuracy, whereupon the amount of organically bound fluorine (i.e. total PFAS) can be calculated. All this, however, only in the ppm range mentioned above. The PFASs currently readily detectable were C4-C13 species in the aqueous phase (US EPA Draft 1633, EPA method currently under development). For the investigated wastewater from semiconductor manufacturing, the detection limit was about 1 ppt. However, it must be noted that almost all of the species included in the analytical interpretation library are not used at all in semiconductor manufacturing, with Perfluorobutane sulfonic acid (PFBS) being the only exception. Thus, the applicability of this method is mainly limited to the detection of PFAS by-products. Whether the existing laboratory capacity will be even slightly sufficient for the determination of all more than 12000 PFAS in the future may be highly doubted. The preparation of the measurements is relatively time-consuming and thus cost-intensive, which, together with the lack of capacities, is likely to lead to exponential price increases in analysis. It is likely that these increases can only be passed on partially, or not at all, to our globally acting customers. This represents a clear disadvantage for European semiconductor manufacturing in global competition. |

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| 9531 | Date:  2023/09/25 20:53  Content:  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  We are using PFAS in MEMS devices in our Electronics in sensory measurement equipment of our machines. It is the essential building block in our optics without any alternatives. Please also notice the other contribution of MEMS uses submitted for the consultation. The attachment is in German. |
| Answer to specific info request 1:  semiconductor devices /Electronics in sensory measurement equipment |
| Answer to specific info request 6:  Please see attachment. |

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| 9532 | Date:  2023/09/25 20:55  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  MANN+HUMMEL Water and Membrane Solutions  Org. country:  Germany | General Comments:  Although we support a selective ban of per- and polyfluoroalkyl substances PFAS, we are of the opinion that polyvinylidene fluoride (PVDF) should be excluded from the current proposal for PFAS restriction. This opinion is also in line with the current evaluation of the Environmental Protection Agency (EPA). PVDF is a unique and versatile fluoropolymer with a wide range of industrial applications. It offers exceptional chemical resistance, high thermal stability, and superior mechanical properties. PVDF has been extensively studied and proven to be safe for use in various applications and is highly resistant to breakdown in the ambient environment based on several regulatory assessments. This includes also in particular the manufacturing and beneficial application of membranes, especially membranes used in the wastewater and water filtration. We firmly believe that a balanced and scientifically sound approach is crucial when developing regulations related to PFAS. Excluding PVDF from the proposed restrictions will allow industries to continue benefiting from its exceptional properties without compromising safety or functionality. By excluding PVDF, we can ensure that the regulations target the appropriate PFAS substances, while avoiding unintended consequences for materials that have been thoroughly assessed and deemed safe. |
| Answer to specific info request 1:  Membrane and wastewater, water filtration solutions This sector is not specifically mentioned in the Table 9 of the ANNEX XV restriction report. |
| Answer to specific info request 2:  What sets PVDF apart in our industry is not only its superior performance but also its contribution to sustainability. Filters and membranes made from PVDF have an extended service life, often up to 10 years or more whereas other water filtration solutions require replacement after five years. This longevity minimizes the need for frequent replacements, reducing waste and conserving resources. PVDF-based filtration products do not release harmful substances into the environment during their operational life. This is a crucial factor in maintaining water quality and safeguarding public health. Due to climate change we are facing droughts and water shortage especially in southern countries. Membrane-based water and wastewater treatment systems contribute to a recycling and reuse of our very limited freshwater resources. 60-77 % of these systems are based on PVDF membranes and a ban would strongly impact a safe and economical supply of clean water to public. |
| Answer to specific info request 3:  Membrane-based products are operated typically for 5 to 10 years’ service life dependent on the product category and application. Our current investigation show that the membrane properties are also intact after over 10 years of operation in wastewater systems from reference plants indicating that the overall polymeric structure of the membrane is not significantly mechanically or chemically impacted. Therefore, it is assumed that the emissions of PVDF are considered negligible over the lifetime of the product. |
| Answer to specific info request 4:  Since the membranes are operated in water and wastewater treatment systems, the membranes are typically disposed according to the local requirements. The membranes consistent of different plastic (polymeric) materials, which are typically disposed through municipal waste treatment. Alternatively, a downcycling and usage as additives in the construction area is a possible path. |
| Answer to specific info request 5:  The water and wastewater industry set strict standards to the usage of products for these specific areas. Especially in the drinking water section strict regulatory requirements apply, where leachate testing is to be performed as part of the product acceptance. During this testing water is recirculated through the membrane module and the effluent is analyzed for specific contaminants. There is no data found which indicates that PFAS leaches from PVDF during these specific tests considering the current state of the art of analytical standards and methods. Overall, the consumption of PVDF in one product must be also considered in relation to the throughput of water in its lifetime. For wastewater treatment plants, it is assumed that we have a total service life of minimum 5 yrs. It is considered that a series product used for wastewater treatment includes 11.25 grams of PVDF within the membrane filtration product, whereas the total membrane area is equal to 500 m2 in one membrane bioreactor module. Considering the throughput of 7500 L/hr, it results in a total throughput of 324,975,000 Liter over the lifetime. This results in 0.035 µg of PVDF in relation to 1 Liter of produced water. Therefore, also a possible leaching would result in an insignificant release of PVDF. |
| Answer to specific info request 6:  Although alternative membrane materials as polyethylene, polypropylene, polyamide, polyethersulfone (PES), and cellulose acetate are available, PVDF is considered as the first choice due to its unique properties as described previously. Especially for hollow fiber membranes, the mechanical stability and especially high tensile strength of reinforced fibers (>600 N according, ASTM D 3822) are considered as a unique advantage. PES is considered as an alternative but is considered as less chemically and mechanically resistant compared to PVDF. This is especially relevant as the membranes used in water treatment need to be cleaned under harsh chemical conditions to guarantee the safety and reliable availability of clean water. Therefore, membrane manufacturers focused on PVDF based membranes. Since the service life of membranes for water and wastewater systems is between 5-10 years, a significant amount of time is to be spent in development of new products and especially for the validation in the field. In addition, it must be taken int account that municipal water and wastewater projects do have a cycle of 3-5 years from planning to execution. Hence, a long transition phase of minimum 10 years would have to be considered for a new development till implementation of a new product for these segments. With respect to drinking water applications new membrane materials and membranes need to be certified by NSF61 and according to local requirements which are defined for each country individually (i.e. Germany has its own regulation for drinking water which is termed KTW). These certification processes usually take 1-3 years. |
| Answer to specific info request 8:  Freshwater is becoming a more and more important and rare resource. Therefore, the European Framework Directive will focus more on water reuse and a better quality of our freshwater. Germany released a new national water strategy where 10 strategic themes are defined. Number 1 is defined as - Protect, restore, and ensure a semi-natural water regime for the long term – prevent water scarcity and conflicting goals. Spain as the main producer of vegetables and fruits in Europe is investing 14.9 billion € in water projects, whereas 12 billion € of the investment will support projects for water reuse besides desalination, optimizing of pipelines etc. Membrane filtration is considered as the key technology to ensure an optimum reuse of our water bodies, whereas PVDF accounts to 60-77 % of used polymers in membranes. A ban would result in a shortage in supply and a significant higher financial invest for producers, OEMs, municipalities and eventually costs would be transferred to the public and each individual. In addition, we would not just risk a shortage in freshwater supply but also a shortage in daily food supply. Also, there is a risk that essential investments would be delayed due to the availability of membranes within the market. |

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| 9533 | Date:  2023/09/25 21:00  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Switzerland  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Confidentiality is requested as it is necessary to protect the legal and business interests of the submitter, a corporate entity, because the submission contains undisclosed intellectual property, including patentable subject matter and trade secrets, and proprietary business plans. Disclosure would undermine our commercial interests and impair our ability to protect intellectual property. | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductor Electronics – heat transfer fluid for immersion cooling Two-Phase immersion cooling [2-PIC] is proven to dramatically reduce the capital cost [61% reduction in building size, 32% reduction in land use], operating cost, greenhouse gas emissions and water consumption of modern datacenters. It is the only cooling technology able to accommodate the power density and interconnect requirements of modern artificial intelligence (AI) computer hardware without impacting the cost, efficiency, and safety metrics. 2-PIC requires fluorochemicals fluids, specifically fluoroketones [FK] and hydrofluoroolefins [HFO], that represent a subset of “PFAS” that would be restricted under the broad definition currently being employed by ECHA in Annex XV. Unlike other subsets that motivated the planned restrictions, these fluids have excellent toxicity profiles [non-toxic], are non-bio accumulative, and non-persistent in the environment. These fluids partition to the atmosphere, have ultra-low global warming potentials, and degrade to naturally occurring substances. They are manufactured by means that do not produce compounds of the type that motivated the planned restrictions. In short, restriction of this class of chemicals is outside the spirit of the intended regulation and no technically and economically feasible alternatives are available. We highly recommend and request ECHA for unlimited derogation or exemption from restriction of these chemistries in 2-PIC applications. Additional information is provided in the attached file. |
| Answer to specific info request 2:  a. 1) Manufacture phase – Our submission concerns an end use (direct contact, two-phase immersion cooling for high performance computing and data centers) which requires the use of a fluorinated fluid that is defined as a PFAS in the proposal. Manufacturing emissions of the substance are addressed by other entities under PFAS manufacturing. They are manufactured by means that do not produce compounds of the type that motivated the planned restrictions. 2) Use phase – The annual emissions of fluid during operation of a 2-PIC tank are on the order of 35 g/kW of server power when using a vapor trap temperature of 10°C. (Tuma P.E., The Merits of Open Bath Immersion Cooling of Datacom Equipment, 26th IEEE Semi-Therm Symposium, 2010). Engineering solutions for vapor capture such as carbon adsorption will reduce these losses from a data center. It is estimated that a 1 gigawatt capacity data center would produce approximately 10 tonnes of fluid emission per year. Please see the attached file for additional information. 3) End-of-life phase – Acvtive filtration in the application ensures that used fluid is same quality as new. Therefore, and because the fluid has substantial financial value, it is assumed that fluids will be recycled or reused indefinitely. b. It is expected that 100% of fluid that is not recycled for reuse within the application will be incinerated . Additional information is provided in the attached file. |
| Answer to specific info request 3:  Incineration is an effective waste management option for the types of fluids used in two-phase, data center immersion cooling. US EPA estimates that 99.99% destruction of fluorinated organic compounds can be achieved if temperatures of 1400°C or higher are used in the incineration process (U.S. EPA Technical Brief, Per- and Polyfluoroalkyl Substances (PFAS): Incineration to Manage PFAS Waste Streams, February 2020). The waste management company, Clean Harbors, reported that its incineration process demonstrated >99.99% destruction of PFAS compounds (Industry Dive publication on 23 January 2023 at https://www.wastedive.com/news /clean-harbors-incinerator-pfas-forever-chemicals/640829/). |
| Answer to specific info request 6:  a. One use of a fluorinated fluid compound that has not been covered in sufficient detail is immersion cooling for high performance computing. The information included in the proposal therefore appears to be based upon incomplete information and we appreciate this opportunity to provide supplementary information. Compounds such as nonafluoro-2-trifluoromethyl-3-pentanone (CAS number 756-13-8) have been demonstrated to have the requisite properties to function as a direct contact, two-phase immersion cooling fluid for high performance computing. Research continues on the development of additional atmospherically short-lived, low global warming potential fluids for this use (Chemours Announces Development of New Specialty Fluid for Two-Phase Immersion Cooling: Opteon™ 2P50, https://www.chemours.com/en/news-media-center/all-news/press-releases/2023/chemours-announces-development-of-new-specialty-fluid-for-two-phase-immersion-cooling-opteon-2p50). A large-scale, high-performance data center operating at 1 gigawatt capacity could produce approximately 10 tonnes/yr of fluorinated fluid emissions. Nonafluoro-2-trifluoromethyl-3-pentanone is not environmentally persistent with an atmospheric lifetime of roughly 1 week (N. Taniguchi, T. Wallington, M. Hurley, A. Guschin, L. Molina and M. Molina, "Atmospheric Chemistry of C2F5C(O)CF(CF3)2: Photolysis and Reaction with Cl Atoms, OH Radicals, and Ozone," Journal of Physical Chemistry A, vol. 107, pp. 2674-2679, 2003.). b. 2PIC using fluorinated fluids is the only technology that can simultaneously meet all the performance and safety requirements for large-scale, high performance computing applications. The fluorinated fluids used in direct contact, two-phase immersion cooling for high performance computing require a specific combination of thermophysical, safety, and compatibility properties. Fluids such as nonafluoro-2-trifluoromethyl-3-pentanone display not only a high dielectric strength to prevent arcing but also very low dielectric constant to protect signal integrity which is essential in high performance computing. The fluids possess sufficiently low viscosity as well as high enough heat capacity and vaporization enthalpy to facilitate efficient heat transfer. This results in significant reduction in data center energy consumption. The fluids are nonflammable and demonstrate low toxicity allowing their use in an occupied data center. The dielectric fluids also exhibit excellent materials compatibility, preserving the operating life of the electronic hardware thereby reducing electronic waste. c. We estimate >100 companies will be affected by the restriction, ranging from device manufacturers to data center operators and users. d. No technologically and economically viable alternatives exist today. No technology is currently available or in development that can adequately replace the use of a fluorinated fluid in direct contact, two-phase immersion cooling for high performance computing. Not-in-kind technologies have been used to remove the heat generated in data centers, including air cooling (forced convection) and immersion in a single phase, hydrocarbon oil (both synthetic and fluids derived from natural sources). However, these cooling technologies are insufficient to meeting the heat transfer demands of high-performance computing such as that required with artificial intelligence. The proximity of devices and resulting high power density which enables these computations is not sufficiently cooled by conventional heat transfer methods such as air cooling or single phase, dielectric liquids. Thus, although the demand for high performance computing continues to grow, no alternative to the currently used fluorinated fluids is currently available which can meet the technical, performance and safety requirements . e. Cooling computer hardware by direct immersion in a dielectric fluid has been conducted on a commercial scale for nearly 40 years. The Cray-2 supercomputer debuted in 1985 using liquid immersion cooling with a fluorinated fluid. The extremely high density of components required to achieve the supercomputer performance requirements was not able to be effectively cooled with air or oil. “Effective cooling techniques are central to the design of high-speed computational systems.” (The Cray-2 Series of Computer Systems, Cray Research, Inc., 1988). Through today, high performance computing continues to rely upon fluorinated fluids to meet its intense cooling needs. Decades of research has been conducted as industry searched for safe, environmentally sustainable chemistries for refrigerants and heat transfer liquids (J. Chem. Eng. Data 2020, 65, 4176−4193). New compounds have been developed to overcome environmental concerns associated with ozone depletion and climate change. Some applications have also been able to return to the use of flammable hydrocarbons through system design changes. However, no technology has been able to simultaneously meet the demanding performance and safety requirements of high performance computing applications other than a fluorinated fluid. Traditionally, datacenters have relied on air-based solutions to dissipate heat, primarily employing three methods: (1) chiller-based cooling, (2) water-side economized cooling, and (3) direct evaporative (free) cooling. Chiller-based cooling employs a closed-loop system featuring a water chiller, while water-side economization incorporates cooling towers to lower water temperatures through evaporation. In response to escalating chip temperatures, liquid cooling has been introduced by cloud providers. Initial implementations typically involve placing cold plates on the most power-intensive components. These cold plates facilitate the flow of fluid through them and the associated piping to effectively dissipate heat from these components. However, this approach demands tailored design and manufacturing of cold plates for each new component, adding complexity to engineering and prolonging time-to-market. Additionally, even with cold plates in use, air cooling is often still required for other components. Microsoft Corporation published a comparison summarizing the advantage of 2-PIC with alternatives (Misra, P.A., et al. (2022). Overclocking in immersion-cooled datacenters. IEEE Micro, 42(4), 10–17.). The comparison demonstrated that 2-PIC provides more than twice the server cooling capacity while consuming less than half the cooling power of the nearest alternative due to its more efficient heat transfer. Please see the attached file for additional details. In our assessment of overall performance comparison 2-PIC was clearly the only technology that can simultaneously meet the demanding performance, economic and safety requirements for current and emerging needs of this societally important technology. The attached file provides a comparison table and additional details. g. Worldwide demand for digital services continues to expand at an increasing pace and with it an ever-increasing requirement for energy by data centers. The International Energy Agency (IEA) estimates that data center energy consumption accounts for ≥1% of worldwide electricity consumption. According to IEA, the share of data center energy use is significantly higher in countries with growing data center markets: Data centers accounted for 18% of the total energy consumption by Ireland in 2022; Data center energy demand is estimated to rise to 15% in Denmark by 2030. The use of 2-PIC presents a unique opportunity to make the next generation of computing technology and data centers significantly more energy efficient. Reduced energy consumption will result in lower energy-generation emissions and contribute to achieving the EU climate objectives. Without 2-PIC, development of the most advanced, high-performance computing applications will be severely inhibited. This will have a direct impact on the advancement of technologies such as artificial intelligence (AI) and applications of it such as machine learning. A briefing for the European Parliament acknowledges that “Artificial intelligence plays an increasingly important role in our lives and economy and is already having an impact on our world in many different ways.” As OECD stated in its 2023 assessment “Policy makers and actors across research systems can do much to accelerate and deepen the uptake of AI in science, magnifying its positive contributions to research. This will support the ability of OECD countries to grow, innovate and address global challenges, from climate change to new contagions.” The anticipated benefits of AI through productivity gains and innovation will stall without the continued advancement in computing technology which is currently dependent upon the use of a fluorinated fluid to safely and effectively meet cooling requirements. References and additional details for each of these elements are provided in the attached file. |

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| 9534 | Date:  2023/09/25 21:05  Content:  Scope or restriction option analysis  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:  Agoria  Org. country:  Belgium  Attachment: | General Comments:  The proposed PFAS restriction covers more than 10.000 substances, which have a broad application within the technological solutions provided by the members of Agoria. Most of our companies have articles/products containing PFAS in their production processes and only limited use PFAS as a substance within their production process. It is in that perspective impossible to give an exhaustive overview of all concerned sector(s) and (sub-) uses in detail. But given the unique combined properties of PFAS, the substitution in multiple uses is challenging without any proper view to date on the potential alternatives.  For our companies there are several major challenges faced with this very broad restriction: • An important challenge is to identify all different PFAS present in their complex products with a dynamic, broad and international supply chain, • Besides the identification, it is equally challenging to find suitable alternatives in a short period of time as proposed within the restriction, if at all suitable alternatives are already existing. • In the complex production processes of our companies also multiple PFAS containing articles are fulfilling a crucial role (filters, sealings, etc…). As for the products, identification is rather difficult, finding a substitution is challenging and will in all cases involve a complete redesign of installations with a significant investment cost, • Also maintenance and repair will become challenging. Both for the products our members are supplying which are containing PFAS as well as in the production processes of our members. After the restriction it will be impossible to exchange in an existing product/installation certain PFAS containing articles/products given that the functionality is not the same within an existing design.. |
| Answer to specific info request 1:  The use of PFAS in heating, ventilation, air conditioning, cooling and refrigeration equipment High end-sealing applications, filters, gaskets, coatings, The use of PFAS in batteries as binder, The use of PFAS in semiconductor production, The use of PFAS in industrial installations |
| Answer to specific info request 2:  In the submission some qualitative information is presented on the different end-of-life options of the several applications for which we are submitting some comments |
| Answer to specific info request 3:  For certain uses more information is added on the treatment options end-of-life |
| Answer to specific info request 4:  Specific on the plastic recycling but also in general elements on the impact the restriction will have on the life-time extension of certain products due to potential challenges in maintenance, repair, re-use ... |
| Answer to specific info request 6:  For the different applications within the contribution we indicate the availability, challenges and timelines needed for the substitution of PFAS |
| Answer to specific info request 7:  For all different uses Agoria submits some proposals for proper derogations in order to avoid the potential negative impact of the proposed restriction with a description of the potential impact if no suitable alternatives are found |

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| 9535 | Date:  2023/09/25 21:11  Content:  Environmental emissions  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  National NGO  Org. name:  Norwegian Hydrogen Forum  Org. country:  Norway  Attachment: | General Comments:  Dear reader, The attachment in section IV reflects the input from the members of Norwegian Hydrogen Forum and will go further into detail on what types and where PFAS is used in the hydrogen value chain, status on the alternatives and consequences of a PFAS ban in the hydrogen sector. See attachment for more reasons and sources.  PFAS is essential in many crucial technologies throughout the hydrogen value chain, such as electrolyses and fuel cells, storage applications, infrastructure and refueling stations, to name just a few. There are no alternatives on the market today or in the foreseen future that can replace PFAS in these applications. There are strong R&D efforts going into researching alternatives to fluoropolymers, but they are still significantly inferior in terms of the duration and stability needed.  The fluoropolymers used in the hydrogen value chain meet the OECD criteria to be defined as ‘polymers of low concern’ (PLC), and do not pose a risk to human health or the environment.  Hydrogen is key to decarbonizing the global energy system and hard to abate sectors in order to reach the ambitious climate targets. A rushed PFAS ban without exemptions for applications in the hydrogen sector would jeopardize the achievement of EU’s Hydrogen Strategy, REPowerEU targets and of the Green Deal objectives.  Based on this, there should be an exemption for the use of PFAS in the hydrogen industry. |
| Answer to specific info request 1:  Energy sector |

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| 9536 | Date:  2023/09/25 21:14  Content:  Environmental emissions  Type:  BehalfOfAnOrganisation  Org. type:  Academic institution  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The results shall be published as original data in a scientific journal. | General Comments:  TFA contamination of the environment / water / plants |
| Answer to specific info request 5:  Whatever PFAS compounds are included in the derogations: be aware of the potential via degradations products, especially the persistent TFA |

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| 9537 | Date:  2023/09/25 21:19  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  European Tyre and Rubber Manufacturers' Association  Org. country:  Belgium  Attachment: | General Comments:  This contribution builds upon ETRMA's initial submission to the July 2021 call for evidence. Its objective is to gauge the extent and consequences of implementing a restriction on PFAS within the tire and General Rubber Goods (GRG) industries. Given the intricacies of the definition and the extensive scope of the restriction, ETRMA members are currently in the process of appraising the presence of PFAS and assessing their effects on the tire and GRG sectors. Consequently, the data and estimates presented here are conservative. ETRMA intends to provide a more comprehensive analysis in the upcoming ECHA consultation. This contribution also follows ECHA guidance. Properties and uses: ETRMA members use mainly fluoropolymers, alongside BPAF as a cross-linking agent, which are part of the PFAS substance family, to produce rubber goods. For the General Rubber Goods (GRG) sector, fluoropolymers, and in particular fluoroelastomers, are used in the manufacturing process of rubber articles. They are also used in the machinery and equipment required for the manufacturing of rubber articles. For the production of tyres, fluoropolymers are not used as raw materials nor components, but FPs are only used in the functioning of some machinery and equipment during the production of tyres. Fluoropolymers meet unique properties such as being virtually chemically inert, non-wetting, non-sticking, and highly resistant to temperature and wear (with low migration values). Fluoropolymers used by the rubber industry, such as FKM or PTFE are chemically, thermally and biologically stable; they do not present significant toxicological concerns and cannot degrade into other smaller PFAS. They are used during the manufacturing phase of the different rubber articles to give the finished product special properties, such as avoiding surface corrosion in extreme conditions. The machinery used throughout the entire tyre production, from the rubber compounding phases until the last curing stage, requires strong anti-sticking properties, and for this purpose, fluoropolymer coatings are needed. Fluoropolymers specific properties make them irreplaceable in a series of technological applications, such as in automotive, aerospace, defence, medical devices, semiconductors, industrial machinery and equipment, energy, oil and gas, many of which of great value for European society, being the basis for digital and green transitions, for example, lithium-ion batteries for electric mobility. Life-cycle assessment: Fluoropolymers are considered to be polymers of low concern posing negligeable risks to human health and the environment. The releases to the environment of polymeric PFAS used in rubber goods and the tyre manufacturing process are expected to be low: during the manufacturing phase, releases appear to be low thanks to the various risk management measures in place and the professional settings; during the use phase, thanks to the stability and non-degradability of fluoropolymers, no significant amount of non-polymeric PFAS is present in the fluoropolymers and therefore the release of non-polymeric PFAS could be considered negligeable during the product lifetime; finally, during the end-of-life phase, any potential polymeric PFAS release would mainly be due to the inadequate treatment of end-of-life general rubber goods articles containing fluoropolymers, as those are treated as industrial waste by professionals. Further measures to address any potential release through the manufacturing of rubber articles and tyres, and through the collection, sorting and process of end-of-life would effectively control the risk for emission of PFAS from rubber articles containing fluoropolymers. Substitution efforts: To date, there are no technically suitable and economically viable alternatives. Finding alternatives and substitution (if possible) is highly time-consuming process due to the complexity and to the number of the affected products. This cannot be achieved in the 18-month transition time proposed by the Dossier submitter. In the GRG sector, fluoroelastomers, or in general fluoropolymers are used only in applications where operating conditions require their unique properties, and there are no known alternatives to their current uses where fluoropolymers are crucial to ensuring the safety and durability of the products. In tyre manufacturing applications, due to the unique characteristics of fluoropolymers (anti-sticking, low coefficient of friction, resistant to wear), there are no known alternatives that are currently available for uses of polymeric PFAS, or, more precisely, fluoropolymers, where they are used as lubricants and non-stick coatings, under harsh conditions or for safe functioning and safety of equipment. This use was not identified as such in the restriction proposal. From the general availability of a technically feasible alternative, ETRMA member companies estimated that more than 15 years are necessary to complete transition activities (i.e., implementing the substitution of PFAS) from the moment when an alternative is identified, which is not the case. Socio-Economic impacts: The total monetized impact of including fluoropolymers in the scope of the proposed restriction on the GRG and tyre industry is estimated at 1.4 billion EUR, including: the total economic impact in the EEA for more than 404 million EUR and social costs of unemployment estimated at least of 1 billion EUR. The estimates reported in this Impact Assessment report should be considered as a lower bound of the expected impacts of a potential ban. Further analysis is required to provide sector-specific impacts and more precise figures for social and environmental risks. Therefore, the cost-effectiveness ratio is expected to be considerable and the restriction for the tyre & rubber sector highly disproportionate because only applying to a minor contributor of the total PFAS input in the environment. Furthermore, the restriction will have wider economic impact such as: a major competitiveness loss to many downstream user industries, such as (non-exhaustive list) automotive, aerospace, defence, medical devices, semiconductors, industrial machinery and equipment, energy, oil and gas; a loss of competitiveness as rubber goods made of fluoropolymers for critical strategic applications will not be available for use in the EEA, while still available in the rest of the World. ETRMA request: Scientific knowledge on polymeric PFAS shows that fluoropolymers are of low concern, being chemically, thermally and biologically stable. Therefore, they should not be included in the scope of the proposed restriction in the same way as non-polymeric PFAS, and major data gaps need to be addressed before any regulatory provision is considered. If fluoropolymers are not excluded from the scope, considering that the duration of derogations is granted according to the availability of suitable alternatives, a time-unlimited derogation is requested for their placing on the market and uses in the general rubber goods and in tyre manufacturing processes. This request is founded on the absence of any technically and economically viable alternatives to date. It should be noted that a minimum of 15 years would be necessary to transition to any substitute once it becomes accessible, and the socio-economic consequences of such a change would be disproportionate. Furthermore, such a derogation should be granted to avoid important shortages of tyres and rubber goods which are essential to automotive, health, aerospace and defence, food, energy, oil and gas, marine, nuclear, digital industries. The impacts on society in the EEA could be considered as disproportionate compared to the benefits of this restriction. |
| Answer to specific info request 1:  The PFAS uses could be split in four types: fluoroelastomers as major ingredients of rubber compounds / articles (presented in section 2.1.2); fluoropolymers coatings of non-PFAS materials, e. g., in pharmaceutical packaging / food-contact materials (presented in section 2.1.3); BPAF as crosslinking agent in fluoroelastomer compounds (not further discussed below because it is included into an ongoing REACH regulation on BPA); fluoropolymers used in the tyre manufacturing process (presented in section 2.2.1). In addition to the above uses, some fluoropolymer-based pieces and lubricants are also present in the production machinery of both GRG and tyres, not in contact with rubber, but these uses common to all industries will not be specifically developed in this document as this is a preliminary assessment. GRG uses Rubber goods containing fluoropolymers are used in (non-exhaustive list): Aerospace; Automotive Light Vehicles; Chemical, Pharma & Food End Use; Agriculture Equipment; CPI Processing Equipment & Machinery; Defence; Electro-Technical / Electronic; Energy; Fluid Power; Healthcare & Medical (including medical devices); Laminated tanks for storage of chemicals; Machine Tools / Presses; Marine; Military; Petroleum activities (apart from firefighting foam); Raw Material Processing – Pulp; Robotics; Sanitary Industry; Semiconductors; Transportation (including Aerospace, automotive, Trucks, Buses, Rail); TULAC (gloves, i.e., personal protection equipment); Oil & Gas (including mining). Rubber goods containing fluoropolymers are used inside other complex objects, such as aviation or automotive, in industrial controlled environments or construction sites. Its use is essential to fulfil a modern society needs and cannot be substituted by other alternatives as it would create a breach in rubber goods performance and ultimately an impact on safety and welfare. Tyres uses Fluoropolymers (generally thermoplastics) are used in some bulk pieces and coatings in contact with rubber during the tyre manufacturing process, to ensure no friction and no sticking during all the steps of the manufacturing process in a plant (rubber compounding, rubber conveying operations, tyre assembly, curing etc.). The most common fluoropolymers used are PTFE (CAS 9002-84-0: Ethene, 1,1,2,2-tetrafluoro-, homopolymer), PFA (Tetrafluoroethylene-Perfluoroalkyl Vinyl Ether Copolymer) and FEP (CAS 25067-11-2: Tetrafluoroethylene-hexafluoropropene copolymer). As examples, these fluoropolymers pieces or coatings can be found in guides, galley rollers, rolling disks, tables, blades, metallic rolls coating and curing moulds coating. They are essential for the production of rubber compounds and tyres, in particular to ensure proper demoulding of the tyre after the curing step, in order not to damage tread sculptures. |
| Answer to specific info request 2:  Fluoropolymers contain minimal non-polymeric PFAS content, which means that non-polymeric PFAS compounds are not discharged during subsequent processing stages or throughout the product's lifespan. Similarly, when it comes to the end-of-life phase of these products, the emissions of PFAS can be regarded as negligible since they are either incinerated or recycled. According to a recent End-of-life (EOL) analysis performed by Conversio, almost 84% of all fluoropolymer applications are incinerated at the end of their life in energy recovery or thermal destruction processes. The remaining of the collected fluoropolymer waste is landfilled (≃ 13%) or recycled (≃ 3%). As regards landfilling, it should be noted that since fluoropolymers are chemically, thermally, and biologically stable (Henry et al., 2018; Korzeniowski, et al. 2022), they are not expected to transform to dispersive nonpolymeric PFAS when disposed of in a landfill. A recent study presented results from OECD guideline biodegradation studies demonstrating that PTFE is stable and does not degrade under environmentally relevant conditions (and is not expected to significantly contribute to landfill leachate). The possible formation of PFAS (short chain or long chain) during incineration of fluoropolymers was investigated in a peer-reviewed study published in Chemosphere. The study concluded that at the typical conditions foreseen by best available technologies, municipal incineration of PTFE is not a significant source of PFAS. Further investigation was recently performed by Karlsruhe Institute of Technology (KIT), that analysed incineration of post-use samples containing four different fluoropolymers, including fluoroelastomers (PTFE, PVDF, PFA, FKM). This study provides strong evidence that incinerating a mixture of fluoropolymers under representative municipal waste combustion conditions leads to complete mineralization of the C-F bonds, no significant emissions of long-chain PFAS, and no significant emissions of TFA or light fluorocarbons such as CF4 or C2F6. |
| Answer to specific info request 5:  It is estimated that 14-50 kilotons of rubber goods require the use of fluoropolymers, accounting for 0.5 to 2% of the overall production of rubber goods in Europe. More than 22 major downstream industries with their different applications sectors are relying on these specific rubber products for their own productions lines. The key reason why the share of the FP is so small is that fluorinated rubbers are expensive specialty elastomers which are only used in applications in which other (cheaper) rubbers would fail. |
| Answer to specific info request 6:  AOA: To conduct an R&D project aimed to substitute FEP, PTFE, PFA and other fluoropolymers in rubber goods and in tyre manufacturing, all the typical development steps would need to be carried out: R&D conducted by suppliers (in collaboration with downstream users); Regulatory compliance (materials must be compliant with applicable regulations and should meet technical requirements); Reformulation / Re-design; HSE assessment of alternatives to guarantee they are safer than FP (hazards, quantities used, potential releases); Full-scale tests (e.g., laboratory formulation studies, including initial and post-ageing characterization tests), and tests of new manufacturing processes (e.g., manufacture of the rubber mix on an industrial mixer and verification of its processing capacity for the manufacture of parts); Internal approval and certification process (validation) to ensure the alternative does not affect the integrity of the final product (e.g., undermining the safety of passengers); Homologation by customers (this step is crucial not only for tyres and other components, but – especially – for rubber goods applications in critical sectors such as aerospace, defence, medical devices); Manufacturing scale-up and launch: Once a new material is tested and validated, the manufacturing stage can start. From the general availability of a technically feasible alternative, the estimated minimum total development and approval time is 15 years. In other words, not less than 15 years are necessary to complete transition activities (i.e., implementing the substitution of PFAS) from the moment when an alternative is identified, which is not currently the case. GRG Those fluoropolymers, typically FKM or PTFE are chemically, thermally and biologically stable; they do not present significant toxicological concerns and cannot degrade into other PFAS. The substitutes should have the same combination of properties to be able to perform under the extreme conditions. At the present state of knowledge, there are no other products with equivalent resistance to oil, ozone, external aging and chemicals, which also possess good enough tensile strength, elongation resistance, and DRC. The high price of fluoropolymers already ensures that the use of these materials is minimised by the manufacturers. Fluoropolymers are only used when the unique properties of these materials are really needed. One of the problems with the substitution is that search for alternatives must be conducted on a case-by-case basis in collaboration with each specific client. Approval by third parties, e.g., regulatory bodies, is also necessary for some applications. Currently, the industry is already striving to propose alternatives to FP whenever possible, following the client's specifications and conducting lab tests. For instance, to explore alternatives to FP for specific FCM-related uses where fluoropolymers cannot be substituted at the present state of the knowledge, the following steps would be necessary: To conduct a literature search on materials that could withstand the conditions imposed by the client's process; To verify if a potential alternative is applicable and compliant with the relevant standards in the respective industrial sectors. For example, it should be compliant with FDA requirements and EU 1935/2004 Food Contact Materials Regulation and 10/2011 Regulation for Plastics in Food Contact Materials meaning the material under consideration for a potential substitution must be on the positive list. If not, a request for adding this material to these lists should be submitted, along with a dossier and proof of its safety; To formulate and manufacture prototypes; To study their chemical and thermal resistance through aging tests in the laboratory; To check these prototypes against relevant standards (e.g., FDA requirements, EU regulation 1935/2004, NORSOK M 710 Elastomer Seas standards etc.), based on the sector-specific requirements; To provide prototypes to concerned industries for in-situ tests to validate their proper functioning. The key challenge, however, would be the unavailability of suitable materials to address the client’s needs. In this regard, the GRG industry is wholly dependent on the technological progress of its supply chain (i.e., manufacturers of fluoropolymers). Tyres PFASs, or, more exactly, fluoropolymers (FP) are utilized in tyre manufacturing for tasks such as moulding, curing, demoulding, and handling uncured rubber mixtures. Every tyre manufacturing line contains some metallic pieces coated with FP (from rubber compounding to curing). The locations and quantities of these coated pieces vary depending on the type of rubber formulations processed (and their level of sticking tendency), the tyre type, and the available manufacturing processes, machines, and tools at each plant. The key functionalities of fluoropolymers lie in their anti-sticking and anti-friction properties (maintained at higher temperatures), complemented by their excellent wear resistance. Therefore, any suitable substitute for these materials must possess these essential characteristics. To conduct an R&D project aimed to substitute FEP, PTFE, PFA and other fluoropolymers in tyre manufacturing, the following steps will be critical: R&D conducted by suppliers (the product should meet technical requirements); HSE assessment of alternatives to guarantee they are safer than FP (hazards, quantities used, potential releases); Full-scale tests of the coating applications; Tests of new manufacturing processes; Internal approval and certification process to ensure the alternative does not affect the integrity of the tyre undermining the safety of passengers. Even if the description of lubricants detailed in Annexes of Restriction proposal is not complete, ETRMA considers that uses of fluoropolymers in tyre manufacturing presented in the table above are covered by the proposed 12-year derogation for ‘lubricants where the use takes place under harsh conditions or use is for safe functioning and safety of equipment’. Nevertheless, 13.5 years (12-year derogation + 18 month of transition period) are clearly not enough to invent, test, and produce a PFAS-free solution for tyre manufacturing and then to implement it. The overall amounts of FP used in the EU in coatings related to tyre manufacturing might be difficult to assess, because the tyre industry is not a direct customer here, but a downstream user in a long supply chain. However, it is a relatively low amount because of the low coating thickness (100 µm maximum) that has a high impact on manufacturing stability and product performance. SEA: The results of the survey show that the total monetized impact of a non-derogation is estimated to 1.4 billion EUR, including: the total economic impact in the EEA: > 404 million EUR; the social costs of unemployment would be equal to > 1 billion EUR. A potential broad restriction without derogation for general rubber goods would have disproportionate socio-economic implications on the EEA tyre & rubber sector. The companies emphasized that a PFAS restriction would be a serious blow to European production. Several seals product ranges for internal combustion engine applications, high-temperature bearings in the automotive industry, aeronautical applications, and food contact applications would be discontinued, leading to the closure of respective production lines. The process of qualifying substitute products for these applications is time-consuming, spanning years, if not decades, and there is a concrete risk of relocating production to non-EEA countries within this time frame. Qualifications are very long and very complex. Time depends on the availability of a product with equivalent performance developed by suppliers. Nevertheless, manufacturers indicated that it would be extremely difficult, if not impossible, to re-enter the market even if in the future alternatives to FPs are qualified and used, since many of the products are used in critical strategic applications where safety and performance cannot be compromised. As a consequence, there would be a considerable impact on manufacturing, supply and sales of these products in the EEA. For example, the expected income generated through the sales of rubber good products in 2027 (year of the entry into force of the proposed restriction plus 18 months of transition period) likely to be affected by a REACH restriction of PFAS is estimated at > 449 million EUR/year (rounded). In terms of sales volumes, this corresponds to > 1.6 billion units/year that would be impacted by the restriction, including, for example, vibration damping parts, static seals for internal combustion engines, gaskets for car electronics, sanitary thermostat seals, seals for multi-way valves, seals for civil and military nuclear applications, gaskets for various industries, nuclear, defence, as well as thermoplastic parts and gaskets for valve sealing systems. The analysis suggests that, as a result of the proposed restriction, the sector’s total contribution to GVA in the EEA, would lose approximately > 87 million EUR/year, when compared to the baseline scenario (i.e., assuming no PFAS restriction). Over four years (the time period suggested by SEAC when there is no suitable alternative available in general), the total economic impact amounts to approximately > 323 million EUR (NPV, 3% d.r.) for participating companies. As mentioned before, the survey does not cover the whole EEA tyre & rubber goods market. The market share covered by this survey represents approximately 80% of the whole EEA market for tyres and GRGs. One can use the market share of the manufacturer companies which participated to the survey to extrapolate the total economic impact in the EEA: > 404 million EUR (rounded). As a result of a highly conservative approach, these figures result in an underestimation of the impact and should be considered as a minimum (lower boundary) of the expected impacts of a restriction in the EEA electromagnetic actuators, valves, and sensors that are used in the transportation industry’s supply chain. It is estimated that > 5,220 employees directly involved in the manufacturing and supply chain of PFAS based products will face layoff in the EEA. This is equal to 65% of the EEA based workforce of the participating companies. Here we report the monetization of the likely social costs of unemployment for these workers. The social costs of unemployment would be equal to > 772 million EUR (see details of the calculation in Annex I below). Although companies along the supply chain would face a reduction in sales over the years, we assume for simplicity that the entire workforce will continue working for the other three years. Therefore, one discounts the monetised impact derived above by three years due to the assumed delay in the lay-off, using discount rate of 3% per year, as follows: 772 million EUR x (1 + 0.03)-3 = 706 million EUR (rounded). Further details of the calculation can be found in Annex I. Once again, we can use the market share to extrapolate the total social impact of the unemployment in the EEA. At the level of tyres and GRG manufacturers, the total impact from unemployment in the EEA caused by a restriction of PFAS is estimated at least 1 billion EUR. |
| Answer to specific info request 7:  In general rubber goods (GRG) fluoropolymers have been already substituted where it was feasible. With fluoropolymers being expensive, they are currently used only in specific critical applications, where the resistance of the GRG to extreme conditions and biosafety are critical. Based on the current R&D activities, there are no known alternatives for use of fluoropolymers in GRG requested to perform in extreme environments (oil and gas industry, military) or to ensure high safety level (automotive, aerospace, medical devices and medical applications, Food Contact Materials, construction). To date, the researchers have not been able to identify technically suitable and economically viable alternatives to PFAS in these specific applications. In tyre manufacturing applications, there are no known alternatives that are currently available for uses of polymeric PFAS, or, more precisely, fluoropolymers, where they are used as lubricants and anti-stick coatings. Fluoropolymers are critical for manufacturing of tyres due to their unique characteristics, which are broad range temperature resistance, anti-sticking, low coefficient of friction and resistance to wear. To date, the relevant supply chain has not been able to identify technically suitable and economically viable alternatives to fluoropolymers. Implementing a re-design requires long timelines and converting the entire ETRMA member companies’ portfolios implies high costs. As these companies are downstream users for PFAS- based commodities, substitution timelines are highly dependent on the ability of the supply chain to supply adequate information and their capabilities to offer suitable alternatives. Timelines are difficult to predict and highly subject to uncertainty. The whole process of identifying suitable alternatives could take many years. From the general availability of a technically feasible alternative, ETRMA member companies estimated that not less than 15 years are necessary to complete transition activities (i.e., implementing the substitution of PFAS) from the moment when an alternative is identified, which is not the case. As a relatively low amount of FP (compared to negative impacts of a FP restriction on the European economy) is involved, and these FPs are handled in industrial and professional settings, a time-unlimited derogation for these applications will be reasonable. This Impact Assessment report identifies the main potential negative consequences that the EU society at large would face in the framework of the non-derogation for fluoropolymers used in GRG and tyre productions process. It has been performed in line with existing ECHA guidance under regulatory processes (REACH), in a spirit of methodological coherence. The results are based on a survey focused on the EU industry, with market share coverage of approximately 80% of the EU market. It therefore provided sufficiently reliable data for a representative extrapolation of the EU market. ETRMA member companies support the phase-out of the use of PFAS wherever this is possible. This, however, requires the availability of technically and economically viable alternatives which are to date not readily available. Finding alternatives is not guaranteed, and substitution (if possible) is a time-consuming process due to the complexity of the affected products. This cannot be achieved in the proposed 18-month transition time. Overall, the results of the IA can reasonably justify a time-unlimited derogation of polymeric PFAS chemicals used in rubber goods applications and the tyre manufacturing process, on the grounds that a non-derogation would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment. It is shown that there are currently no suitable alternatives to the polymeric PFAS chemicals on the EEA market for use in rubber goods and tyre manufacturing process. Developing a substitute for PFAS within 18 months is not considered as a commercially viable option for market operators due to excessively long timelines and high costs. The total monetized impact of a non-derogation is estimated to 1.4 billion EUR, including: the total economic impact in the EEA: > 404 million EUR; the social costs of unemployment would be equal to > 1 billion EUR. The non-derogation also puts at stake some of the political objectives of the European Green Deal, and the transition targets toward a climate-neutral and circular economy. Tyres and rubber are highly recyclable materials, with a well-established and organized circular economy industry. It would also be a loss of sovereignty for an industry in which the European Union is a world leader, going against the 2030 strategy of industrial sovereignty. |
| Answer to specific info request 8:  To analyse the GRG value chain, it is essential to understand the uses made of GRG products by downstream users. Whether in the automotive, aerospace, medical, energy, electronics or construction sectors, rubber products containing PFAS are required at many stages, in many industries. Therefore, here is a non-exhaustive list of the different uses made by downstream users of GRG, as well as an explanation of the technical specifications that require these PFAS-containing products. A PFAS restriction in the EEA's tire and rubber goods manufacturing market would hinder competitiveness, contrary to the EU's strategy to bolster domestic industry. This could affect downstream users highly reliant on rubber products. Automotive Industry: Rubber products are crucial in various automotive applications, supporting millions of jobs, contributing to government revenue, and playing a pivotal role in innovation. The automotive sector employs 13.0 million Europeans, constituting 7% of all EU jobs. It contributes €374.6 billion in tax revenue and has a surplus of €79.5 billion in the EU's trade balance. Moreover, it invests €58.8 billion in research and development annually. Aerospace Industry: In 2019, the European aerospace and defense sector generated revenue exceeding 250 billion euros and employed around 890,000 individuals. Airlines are committed to achieving net-zero emissions by 2050. Rubber components are widely used in civil and military aircraft. Medical Devices: No viable substitutes exist for fluoropolymers and fluoroelastomers in pharmaceuticals and medicine. The chemical industry, including pharmaceuticals, contributed 335 billion EUR in added value in 2018, ranking as the most prominent sector within the manufacturing industry of the EU27. Oil & Gas: A PFAS restriction could halt oil and gas extraction in high-pressure and high-temperature environments due to the lack of alternatives for rubber perfluoroelastomer parts. The EU's energy sector employs approximately 1.6 million individuals and contributes EUR 250 billion in added value to the economy. Semiconductors/Electronics: The semiconductor industry holds 10% of the global microchip market in the EU. The European Chips Act aims to invest over 43 billion EUR to enhance competitiveness. However, a PFAS restriction could lead to the elimination of semiconductor manufacturing in the EEA. Energy Applications: The battery and hydrogen sectors heavily rely on PFAS-containing rubber. A broad PFAS restriction would hinder the development of these sectors. The European Union aims for decarbonized energy production, but a restriction could jeopardize these efforts. Other Impacted Industries: Industries like chemicals, mechanical engineering, and sealing would suffer due to PFAS restrictions. The French Federation of mechanical engineering industries estimates that 600,000 FTEs in employment would be affected by a PFAS restriction, with an expected impact on 80% of the industry's turnover in France. |
| Answer to specific info request 9:  Considering fluoroelastomers, and fluoropolymers in general, they don’t show any chemical similarity with fluorinated surfactants, since: due to their high molecular mass these materials are insoluble in water and not bioavailable; the lack or the very small amounts of functional groups (compared to the molecular mass) make these materials unable to interact with biological systems (non-bioavailable, non-bioaccumulative and non-toxic). There is a strong scientific consensus that fluoropolymers satisfy the widely accepted polymer hazard assessment criteria for polymers of low concern (PLC). The PLC criteria encompass various physicochemical attributes, including factors like molecular weight. These attributes influence the substance's ability to enter biological systems and also serve as indicators of potential risks. Fluoropolymers, due to their substantial molecular weight and insolubility in substances like water and octanol, lack the capacity to permeate cell membranes. This characteristic renders them biologically inaccessible, thereby minimizing worries regarding their impact on human health and the environment. FPs are niche specialty polymers, bio-inert and safe, stable thermally, chemically and very resistant against UV and aging. They fulfil the PLC criteria, and are not prone to generate risks for human safety and environment. Fluoropolymers used by the rubber industry, such as FKM or PTFE, are chemically, thermally and biologically stable; they do not present significant toxicological concerns and cannot degrade into other smaller PFAS. PTFE has been extensively tested to comply with US and EU food contact and global medical device regulations (e.g., USFDA, CFDA, Korea MFDS, Japan PMDA), including ISO 10993 biocompatibility testing and preclinical animal testing. Its superior anti-sticking properties have been recently confirmed in a simulation study. Of course, a complete and sound assessment requires an analysis of the whole life cycle of the fluoropolymer, taking into consideration not only the intrinsic properties of the material, but also: the properties of the substances used for its production and related emissions; the properties and amount of the substances released during use phase; the properties of the substances released at the end-of-life cycle. |

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| 9538 | Date:  2023/09/25 21:24  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  please keep document confidential as it contains sensitive company information and confidential test results | General Comments:  - |

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| 9539 | Date:  2023/09/25 21:29  Content:  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  MemberState  Country:  France  Attachment:    <redacted> | General Comments:  1. Les systèmes d’armes et le secteur de la défense Le Ministère des Armées en France, comme les autres Ministères de la défense des Etats-membres de l’Union européenne, constitue le maillon final de la chaîne d’approvisionnement du secteur de la défense. Compte-tenu de la complexité des systèmes de défense, (un aéronef comporte plusieurs millions de pièces), cette chaîne d’approvisionnement est constituée de nombreux niveaux, et s’appuie sur différents domaines d’expertise au sein de la base industrielle et technologique de défense : essentiellement le naval, le terrestre, l’aéronautique et le spatial, et le domaine transverse des missiles, armes et munitions. Ces domaines utilisent un éventail extrêmement large de technologies utilisant des PFAS, comme l’électronique, la réfrigération, les textiles techniques, vêtements professionnels (incluant les équipements de protection individuels), la pyrotechnie, le nucléaire. Les équipements du secteur de la Défense sont donc particulièrement concernés par le projet de restriction. Les travaux de recensement conduits par la Direction Générale de l’Armement (DGA) depuis 2021 s’appuyant sur ses principaux fournisseurs directs ont montré le recours à de nombreux usages des PFAS, malgré le caractère actuellement très partiel des obligations de communication dans la chaîne d’approvisionnement portant sur les PFAS visés par le projet de restriction (fiches de données de sécurité et article 33 de REACH). Un tel résultat n’est pas surprenant : les systèmes de défense consistent en effet en un assemblage d’équipements ou de produits qui proviennent de différents secteurs qui utilisent des PFAS. Certains de ces secteurs sont évoqués ci-dessus et le dossier annexe XV du projet de restriction confirme une telle utilisation pour chacun de ces secteurs. La spécificité des systèmes d’armes est qu’ils doivent opérer dans des environnements très sévères, notamment en termes de sollicitations mécaniques et gammes de température de fonctionnement et en stockage. Ils doivent aussi pouvoir protéger les forces armées contre des agressions multiples, en particulier nucléaires, radiologiques, biologiques et chimiques. Ils requièrent les meilleures technologies disponibles afin d’atteindre les plus hautes performances, la robustesse et la fiabilité pour disposer d’un avantage dans les combats. L’ensemble des systèmes d’armes a donc recours aux PFAS pour leurs nombreuses propriétés uniques, que ce soit la tenue en température, la résistance aux agressions chimiques, la tenue mécanique, le faible coefficient de frottement, l’isolation électrique, leur constante diélectrique, l’usage comme fluide frigorigène. Ils sont utilisés dans nombre de composants, sous-ensembles ou ingrédients de base (en tant que réfrigérants, agents d’extinction, câbles, composants électroniques, tuyaux hydrauliques, joints et autres pièces d’étanchéité, lubrifiants, adhésifs, mastics …), ou dans les procédés de fabrication (les revêtements et traitements de surface, le démoulage des explosifs, le brasage en phase vapeur de cartes électroniques …). Les systèmes d’armes doivent en outre être maintenus en condition opérationnelle (MCO) pendant toute leur durée de vie, qui peut être très longue. Des équipements tels que des bâtiments de surface, des sous-marins, des avions de chasse ou des chars d’assaut ont une durée de vie de l’ordre de 40 ans. Il convient dès lors de veiller à ce que la future restriction sur les PFAS ne remette pas en cause, par des effets directs ou indirects, les performances des systèmes de défense et leur MCO pendant toute leur durée de vie.  2. Les enjeux du projet de restriction tel que présenté pour le secteur de la défense De manière générale, le Ministère des Armées constate que le projet de restriction revêt un champ d’application extrêmement large, en raison de la définition retenue pour les PFAS : les substances concernées sont très nombreuses, et tous les usages des PFAS sont visés par l’interdiction à de très rares exceptions. Certaines applications de niche ou technologies spécifiques ne sont pas exclues du champ de la restriction, sans que le dossier annexe XV n’apporte les justifications ni n’évalue les impacts de telles interdictions. A titre d’exemple : • En l’état actuel du projet du de restriction, des compositions pyrotechniques au magnésium, Teflon® et Viton® (MTV) utilisées pour la protection notamment des aéronefs seraient interdites de fabrication, sauf octroi d’exemptions défense au titre de l’article 2 paragraphe 3 de REACH (cf. ci-dessous). Des revêtements indispensables à la synthèse ou la fabrication des substances explosives ou compositions pyrotechniques utilisées dans différentes munitions le seraient également. • Les PFAS sont également utilisés dans la fabrication d’un certain nombre de composants électroniques dont certains sont critiques pour les systèmes d’armes, mais le projet de restriction ne prévoit aucune dérogation à l’interdiction de production, mise sur le marché et utilisation de tels composants. En outre, la recherche d’alternatives n’a pas eu lieu pour la grande majorité des applications défense. Depuis la stratégie européenne sur les produits chimiques durables publiée par la Commission européenne en 2020, des travaux de recherche d’alternatives n’ont globalement pas été engagés par le secteur de la Défense, même si des initiatives ont été lancées dans les domaines du textile et des mousses d’extinction de feux d’hydrocarbures (hors périmètre de la restriction). Ces initiatives sont la conséquence de projets de restriction antérieurs au projet de restriction universelle des PFAS. Sur l’ensemble des PFAS visés par le projet de restriction, les travaux d’identification des alternatives n’ont pas encore été menés pour notre secteur ; ils ont seulement été initiés à la faveur de ce projet de restriction ; a fortiori, s’agissant de la qualification des alternatives éventuelles, celle-ci n’a pu débuter pour nos applications. Il n’est donc pas possible de se prononcer de manière générale sur leur acceptabilité en termes de performances techniques, et cela prendra du temps dans les cas où des alternatives prometteuses existeraient. Dans d’autres cas, les PFAS remplacent des produits qui parfois posent des problèmes de sécurité ou de durée de vie. Revenir en arrière pour ces cas se ferait au détriment de qualités intrinsèques des substances assurant le niveau de performance opérationnelle recherché et au détriment de la sécurité des utilisateurs. Pour la grande majorité de nos applications, il n’y a globalement pas de substituts acceptables identifiés à ce stade. De ce fait, au regard de la durée de vie des équipements défense, les durées prévues pour les différentes dérogations – confirmées ou potentielles – semblent insuffisantes pour notre secteur. De surcroit, la durée courte des dérogations par rapport à la durée de vie des systèmes d’armes couplée à l’impact large du projet de restriction laisse présager une impossibilité à assurer le MCO de ces systèmes sur toute leur durée de vie, dans le respect des conditions de leur qualification ou de leur certification initiale, lorsque leur définition initiale nécessite l’utilisation de PFAS. Cette difficulté s’applique également à l’importation de certaines pièces d’aéronefs ou de consommables qualifiés et certifiés contenant des PFAS nécessaires pour l’entretien d’aéronefs fournis par des pays tiers, qui ne serait plus possible à l’expiration des dérogations afférentes, alors que certains aéronefs sont au début de leur service. Il convient également de préciser qu’en amont d’une longue durée de vie, les systèmes d’armes font souvent l’objet de développements s’étalant sur plusieurs années, avec à l’issue du développement une phase de qualification, éventuellement suivie d’une phase de certification auprès d’autorités nationales, européennes ou extra-européennes suivant le type de matériel. Pour notre secteur et en fonction du type de matériel, cela rend d’autant plus faible la durée utile des dérogations proposées à ce stade par le projet de restriction.  3. Demandes pour une restriction prenant en compte les enjeux du secteur de la défense Le Ministère des Armées demande à ce que la restriction sur les PFAS permette, comme l’envisage la Stratégie européenne sur les produits chimiques durables, de ne pas interdire les usages des PFAS qui sont essentiels pour le fonctionnement de la société. Or la Défense des citoyens européens et de leurs Etats contre les menaces extérieures est jugée essentielle pour le fonctionnement de la société, ce qui implique que les Etats soient en capacité de produire et entretenir des systèmes d’armes garantissant leur sécurité et la défense de leurs intérêts essentiels.  Pour le Ministère des Armées, les dérogations suivantes doivent être considérées dans la restriction :  Dérogations pour les applications essentielles de la défense : Usages non couverts par le dossier Annexe XV : - Missiles, munitions, systèmes ou sous-systèmes contenant des substances explosives ou pyrotechniques et leurs constituants pour les forces armées ; \*\* Justification : Usage de PFAS pour lequel aucune alternative n’a été identifiée à ce stade, notamment (Revêtement de missiles et munitions ; Oxydant dans les compositions pyrotechniques, notamment les compositions magnésium, Téflon, Viton ; les compositions retard ; les compositions traçantes ; Substances explosives ; Lubrifiant solide ; Pièces de munitions) - Moyens de synthèse, de mise en œuvre, de fabrication et de contrôle pour la production de substances explosives ou de matières pyrotechniques, munitions et missiles pour les forces armées \*\* Justification : Usage pour lequel aucune alternative n’a été identifiée à ce stade dans les revêtements ou protection des outils de production (synthèse, mise en œuvre fabrication et contrôle) des parties de missiles et munitions en contact avec les matières énergétiques, notamment à fin de sécurité, de facilitation du démoulage et de conservation de la forme des matières explosives.  Usages globalement couverts par l’Annexe XV : Dérogations pour les applications essentielles de la défense: - Textiles des équipements individuels et collectifs conçus spécifiquement pour les forces armées, agents d’imprégnation pour la réimprégnation de ces textiles, textiles pour la filtration et les média de séparation entre milieux utilisés dans les applications militaires à hautes performances. \*\*Durée de la dérogation : jusqu’en 2040 + clause de réexamen pour évaluer les besoins restants après 2040, notamment pour le maintien en conditions opérationnelles. \*\*\* Justification : Les PFAS sont utilisés dans la fabrication d’uniformes militaires afin de garantir à ses utilisateurs le niveau de protection requis par les impératifs opérationnels. Du fait des propriétés hydrophobes et oléophobes des PFAS, ces substances sont utilisées dans les tenues de protection au risque nucléaire, radiologique, biologique et chimique (NRBC) pour lesquels il n’existe pas à l’heure actuelle d’alternatives permettant d’offrir le niveau de protection requis contre ce risque. Les PFAS sont également utilisés pour d’autres applications. Les solutions de substitution actuelles ne répondent pas aux exigences militaires à ce stade. Or les dérogations 5.b et 5.c du projet de restriction ne s’appliquent que dans le champ d’application du règlement (UE) 2016/425, qui exclut les équipements de protection individuelle (EPI) « conçus spécifiquement pour les forces armées ou pour le maintien de l’ordre ». En outre, une dérogation spécifique relative à l’ensemble des usages militaires (textiles, agents d’imprégnation, filtres et membranes) plutôt que plusieurs dérogations éclatées apporterait plus de clarté au texte. - Extension de la dérogation potentielle 5.dd sur les réfrigérants et climatisations mobiles (MAC) dans les véhicules dans les applications militaires (Champ d’application : véhicules, navires de guerre et navires auxiliaires (incluant les sous-marins), aéronefs. ; \*\*Durée de la dérogation : jusqu’en 2040 + clause de réexamen pour évaluer les besoins restants après 2040, notamment pour le maintien en conditions opérationnelles. \*\*\* Justification : Dérogation spécifique pour la génération de froid dans les porteurs militaires, compte-tenu des contraintes militaires déjà énoncées par l’annexe XV : Production de froid dans les bâtiments de surface et sous-marins, notamment pour certaines installations techniques comme la propulsion, pour la réfrigération des vivres, la climatisation, … Refroidissement des systèmes électroniques sensibles.  Dérogation générale pour les autres usages militaires des PFAS: - Hors demandes de dérogation ci-dessus : Production, mise sur le marché, utilisation et maintien en conditions opérationnelles des équipements militaires mis sur le marché jusqu’en 2040+ clause de réexamen pour évaluer les besoins restants après 2040, notamment pour le maintien en conditions opérationnelles ; \*\* Justification : Certains équipements structurants des forces armées en cours de définition et établis sur les technologies actuellement disponibles ne sont livrés au Ministère des Armées qu’après un long processus de conception et de fabrication ; Aucune alternative pour les lubrifiants utilisés dans les équipements militaires, en particulier les aéronefs, n’a été identifiée à ce stade; Aucune alternative pour les applications à fortes contraintes électriques et mécaniques des systèmes militaires n’a été identifiée à ce stade ; Aucune alternative pour les différents types de capteurs sans pertes de performance n’a été identifiée à ce stade, alors que certains composants électriques et électroniques contiennent des PFAS ; Aucune alternative pour Les cartes électroniques hyper fréquence (HF) n’a été identifiée à ce stade, sans pertes de performance ; Plus généralement, la disponibilité d’armements et la recherche de supériorité opérationnelle des forces armées est un enjeu majeur pour la protection des populations, ce qui impose au vu du vaste périmètre du projet de restriction de donner de la visibilité sur la possibilité d’utiliser et de maintenir en conditions opérationnelles les matériels en cours de conception avec des PFAS et dont la mise sur le marché pourra n’intervenir que dans plusieurs années. La disponibilité des pièces détachées doit pouvoir être assurée au-delà de 2040. Une telle dérogation pour le secteur de la défense est de nature à donner de la visibilité au niveau européen sur la poursuite contrôlée de l’utilisation de substances PFAS pour ce secteur ; cette visibilité donnée aux fabricants de PFAS permettra de limiter les risques pour la sécurité d’approvisionnement du secteur de la défense de ces substances essentielles.  Considérations socio-économiques La défense constitue souvent, en comparaison du secteur civil, un marché de niche, malgré le nombre significatif de personnes employées dans le domaine. Par exemple, le volume des connecteurs produits pour les usages militaires est très faible par rapport à celui que les connecticiens produisent pour le domaine civil. Il importe donc pour le secteur de la défense que les nombreux acteurs de sa chaîne d’approvisionnement puissent disposer d’une visibilité à long terme et de débouchés suffisants pour ce marché de niche. C’est pourquoi des dérogations spécifiques et transverses concernant notre secteur doivent être étudiées. Par ailleurs, le Ministère des Armées souligne les conséquences économiques du projet de restriction. Les recherches d’alternatives, les phases de qualification et de certification le cas échéant, entraîneront des coûts importants pour l’ensemble du secteur de la Défense, du fait du nombre d’applications des PFAS utilisés par la Défense, du nombre de substances concernées et du caractère remarquable des propriétés des PFAS qui rendront ardue leur substitution. Au demeurant, il ressort à ce stade en l’état des connaissances et dans certains cas de fortes difficultés voire une impossibilité à l’ensemble des PFAS dans les applications militaires. Sans dérogations pour la Défense et telle que formulée le dossier annexe XV, la restriction est susceptible d’entraîner des pertes de capacité opérationnelles importantes, qui ne peuvent être envisagées. Or la recherche de supériorité stratégique est essentielle pour assurer l’objectif de défense des citoyens face aux agressions extérieures. Sur les théâtres d’opération, accepter de diminuer les performances de nos matériels revient à mettre en danger la vie des soldats face aux ennemis, qui ne sont pas soumis aux règles de REACH pour la fabrication de leurs matériels. Le Ministère des Armées rappelle par ailleurs que le mécanisme d’exemption défense prévu par l’article 2 paragraphe 3 du règlement REACH ne constitue qu’une solution de dernier recours pour le secteur, puisque ce mécanisme ne permet pas d’éviter les éventuels effets d’éviction du marché d’une substance suite à l’interdiction de tout ou partie des usages de cette substance via le régime de restriction ou son inclusion dans le régime d’autorisation REACH. Les industriels de la Base industrielle et technologique de défense (BITD) et le Ministère des Armées sont préoccupés par un tel effet d’éviction sur une part importante de la famille des PFAS, du fait du champ d’application très large du projet de restriction et des annonces d’arrêt de production de certains fabricants de PFAS. Enfin, le Ministère des Armées souligne l’effet délétère causé par l’abandon de la production de familles de PFAS pour lesquels les producteurs estimeraient ne plus avoir de débouchés économiques suffisants.  En conclusion, les PFAS sont essentiels pour la défense et leur recours doit de façon générale être préservé à l’aide des dérogations demandées supra: Un nombre très important d’usages des PFAS ne dispose pas d’alternatives identifiées à ce stade pour les équipements de défense. Aujourd’hui, sans ces substances, certains matériels ne peuvent plus être fabriqués. Par exemple les leurres infrarouge (compositions MTV), sans lesquels il n’est pas possible de protéger les aéronefs de combat contre les ennemis, lesquels ennemis en retireront un très grand avantage tactique. D’autres équipements comme les aéronefs ne pourront plus être fabriqués ou maintenus à long terme à isoperformance et dans les conditions de qualification et de certification initiales, si le marché des substances PFAS s’assèche. Cela occasionnera des baisses de performances très probablement significatives ainsi que des sur-coûts très importants (évolution de la définition des matériels, nouvelles qualifications et nouvelles certifications). Dans l’ensemble, le Ministère des Armées estime que les usages décrits doivent être particulièrement considérés dans le contexte géopolitique actuel.  \*\* In conclusion, PFAS are essential for defense, and their use must generally be preserved by means of the derogations requested above. A very large number of PFAS uses have no alternatives identified at this stage for defense equipment. Today, without these substances, certain items of equipment can no longer be manufactured. Infrared decoys (MTV compositions), for example, without which it is impossible to protect combat aircraft from enemies, who will gain a major tactical advantage. Other equipment, such as aircraft, will no longer be able to be manufactured or maintained over the long term at isoperformance and under the original qualification and certification conditions, if the market for PFAS substances dries up. This is likely to lead to significant reductions in performance, as well as very substantial additional costs (changes in equipment definition, new qualifications and certifications). All in all, the French Ministry of Defence believes that the uses described above should be given particular consideration in the current geopolitical context. |
| Answer to specific info request 1:  Les usages répertoriés ici par le Ministère des Armées sont ceux considérés comme les plus critiques, les plus spécifiques ou d’importance vitale pour la défense. Même si la liste n’est pas exhaustive, y compris sur les applications critiques, elle est toutefois représentative de l’essentiel des problématiques défense remontées à travers la chaîne d’approvisionnement. 1. Secteurs et (sous-) usages Les commentaires de la présente contribution s’appliquent en particulier aux secteurs suivants répertoriés par le dossier Annexe XV, en ce qu’ils font partie de la chaîne d’approvisionnement des matériels de défense. - Fabrication (Annexe E.2.1.) : o Secteur dans son ensemble ; - Textiles et habillement (TULAC - Annexe E.2.2.) : o Vêtements professionnels (incluant les EPI) ; o Textiles techniques ; o Autres :  Textiles pour utilisation dans les compartiments moteurs pour l’automobile (pour le bruit et l’isolement des vibrations) ; - Placage métallique et fabrication de produits métalliques (Annexe E.2.4.) : o Chromage dur ; o Chromage décoratif, revêtement sur plastiques et placage métallique autre que le chrome ; - Applications des gaz fluorés (Annexe E.2.8) : o Réfrigération ; o Climatisation et pompes à chaleur ; o Agents moussants ; o Solvants ; o Gaz propulsifs ; o Moulage du magnésium ; o Agents d’extinction ; o Gaz d’isolation dans les équipements électriques ; - Dispositifs médicaux (Annexe E.2.9.) ; - Transports (Annexe E.2.10.) : o Utilisation des PFAS dans des applications affectant le bon fonctionnement lié à la sécurité des véhicules et affectant la sécurité des opérateurs, des passagers ou des marchandises, dans la mesure où elles ne sont pas abordées dans d’autres parties de cette proposition de restriction (par exemple, sous lubrifiants, équipements électroniques et TULAC) ; o Fluides hydrauliques ; o Climatisation mobile (MAC) ; o MAC et réfrigération dans les applications militaires ; - Electronique et semiconducteurs (Annexe E.2.11.) o Electronique ; o Semiconducteurs ; - Secteur de l’énergie (Annexe E.2.12.) o Secteur dans son ensemble ; - Lubrifiants (Annexe E.2.14.) o Secteur dans son ensemble ; - Pétrole et industries des mines. Néanmoins, il apparaît que des usages spécifiques aux équipements de défense ne sont pas répertoriés comme une catégorie d’usage dans le dossier annexe XV. Les catégories d’usage et sous-usages suivants mériteraient d’être évoquées dans le dossier, même si les quantités concernées sont très faibles : - Usages spécifiques défense o Missiles munitions, , systèmes ou sous-systèmes contenant des substances explosives ou pyrotechniques et leurs constituants pour les forces armées, et leurs moyens de synthèse, de mise en œuvre, de fabrication et de contrôle pour leur On compte en particulier dans ces usages la production et l’utilisation de substances explosives ou matières pyrotechniques composant les explosifs, les compositions pyrotechniques, les poudres propulsives et les propergols. |
| Answer to specific info request 6:  Les usages ci-dessous ne sont pas mentionnées dans le dossier Annexe XV, ou de manière pas suffisamment explicite: Usages « Missiles, munitions, systèmes ou sous-systèmes contenant des substances explosives ou pyrotechniques et leurs constituants pour les forces armées, et leurs moyens de synthèse, de mise en œuvre, de fabrication et de contrôle pour leur production ». Réponse générale à la question d) pour la pyrotechnie militaire : dans ce domaine, on estime qu’il faut en général 10 à 15 ans pour mener à bien des travaux de substitution. Viennent d’abord des travaux de recherche via une thèse, qui durent environ 3 ans et permettent de passer du Technology Readiness Level (TRL) 1 au TRL 3 ; puis sont lancées des études pour atteindre les TRL 5 ou 6 (durée typique : 3 à 6 ans selon difficultés rencontrées). Un marché de réalisation prend la suite (3 à 4 ans). S’ajoutent ensuite les phases de qualification interne et externe, avant la mise en service (1 à 2 ans). Exemple de sous-usage de PFAS dans le domaine : les leurres - Sous-usage : Composition pyrotechnique infrarouge - Fonctionnalité-clé (question b) : Oxydant dans composition infrarouge Magnésium - Téflon - Viton (MTV) - Alternatives (question d) : Pas d’alternatives évaluées à notre connaissance. D’autres exemples de polymères fluorés utilisés pour les applications pyrotechniques sont fournis (cf. pièce jointe confidentielle). Pour complément sur les usages recensés pour la pyrotechnie, les missiles et autres munitions, voir la partie des commentaires généraux relatifs à la demande de dérogation idoine. Autres usages de l’industrie de défense : Les usages ci-dessous ont été recensés, en complément des usages déjà mentionnés dans la partie des commentaires généraux relatifs aux demandes de dérogation (autres que celle relative aux missiles et autres munitions). Ceux-ci sont classés selon les types d’usages recensés dans le dossier Annexe XV. Electronique et semiconducteurs : Applications hyperfréquences - Fonctionnalité-clé (question b) : Notamment, pour les cartes électroniques, Limiter la perte de signal et avoir la résistance thermique indispensable pour la soudure des composants électroniques sur la carte. - Alternatives (question d) : Pas de solutions offrant les mêmes performances identifiée à date. Electronique et semiconducteurs : Soudure en phase vapeur - Fonctionnalité-clé (question b) : Permettre l’homogénéité de la température sur la carte électronique et ainsi éviter les points chauds. - Alternatives (question d) : A date, pas d'alternatives sans PFAS au fluide caloporteur utilisé. Câbles : Différents usages militaires ont été recensés pour les câbles avec des fluoropolymères. Certains usages sont critiques : - Câbles immergés, dans le domaine naval ; - Divers câbles ou gaines pour les batteries utilisées dans certains matériels de guerre ; - Câbles pour capteurs ; - Câbles isolés avec des fluoropolymères dans les aéronefs militaires, pour leurs propriétés de résistance thermique et aux produits chimiques, en sus de leurs propriétés diélectriques. Energie Les batteries utilisées dans certains matériels de guerre utilisent notamment des câbles avec fluoropolymères (cf. supra). S’agissant des membranes à échange de protons (PEM) des piles à combustible et des électrolyseurs, certaines applications de défense y ont recours pour éviter la fragilisation des structures métalliques induite par l’hydrogène dans la pile et l’ensemble de la tuyauterie. Lubrifiants : Le recours aux PFAS comme lubrifiants est essentiel pour le secteur de la défense. Les usages suivants de PFAS non polymères ont été notamment recensés : - Des agents de nettoyage / solvants non fluoropolymères sont utilisés pour certains systèmes électroniques essentiels ; - Lubrifiants dans de nombreux systèmes de défense. Autres équipements et consommables des forces armées ayant recours aux PFAS Parmi les autres équipements et consommables des forces armées ayant recours aux PFAS et dont les usages ne sont pas spécifiquement mentionnés dans l’annexe XV, les éléments suivants peuvent être cités (liste non exhaustive) : - Non fluoropolymères : adhésifs dans les outils de production de certaines munitions ; - Fluoropolymères pour capteurs. En résumé, même si la liste des usages défense présentés ici ne peut être ni exhaustive ni très précise quant aux équipement en raison de la sensibilité de ces informations, il apparaît que les PFAS sont utilisés de manière transverse sur un large éventail de matériels spécifique défense. |
| Answer to specific info request 7:  Utilisation comme réfrigérants et pour les climatisations mobiles (MAC) dans les véhicules dans les applications militaires jusqu’à 13,5 ans après l’entrée en vigueur (dérogation 5.dd) et autres usages de réfrigération spécifiquement militaires. Cette dérogation potentielle appelle les commentaires suivants : de manière générale elle est jugée essentielle pour les applications militaires, compte-tenu des contraintes militaires spécifiques indiquées dans l’annexe XV. Elle devrait également être précisée et bénéficier d’une durée adaptée à celle des équipements militaires concernés. Insuffisance du terme “véhicule”: Le terme “véhicule” utilisé dans la dérogation est insuffisant ; il est en effet généralement utilisé en référence aux seuls véhicules du domaine terrestre. Il conviendrait donc d’y ajouter les navires de guerre et navires auxiliaires ainsi que les aéronefs, pour couvrir explicitement les domaines naval et aéronautique. Les sous-marins sont considérés comme compris dans l’expression “navires de guerre”. Insuffisance de la durée de dérogation (cf. « Calendrier pour la transition », annexe E p. 359): Comme évoqué en partie générale, les systèmes militaires ont une durée de vie de l’ordre de 40 ans ; celle-ci peut aller jusqu’à une cinquantaine d’années. Même si l’étude mentionnée dans l’annexe XV (Hill, 2003) évoque une transition pour l’introduction pour la production des véhicules de 2 à 4 ans, cela apparaît impossible dans le domaine militaire. En effet, la durée de conception d’un système militaire est longue ; il peut s’agir d’une dizaine d’années. Dès lors, des programmes en cours de commande aux industriels ont déjà dû opérer des choix en matière d’utilisation de HFO et de HFC ; ces systèmes seront pour partie livrés jusqu’en 2030, d’autres ne seront livrés qu’à horizon 2040. En outre, en particulier lorsque ces systèmes relèvent du domaine naval, le maintien en conditions opérationnelles ne peut être comparé à l’entretien des voitures particulières. En effet, certains systèmes sont sujet à deux types d’entretien : les entretiens mineurs et les entretiens majeurs. Les entretiens majeurs sont planifiés environ une fois tous les dix ans, et font l’objet d’une planification technique et budgétaire qui ne s’improvise pas. Cela explique que le recours aux HFC et à plus long terme aux HFO reste indispensable, pour concilier l’évolution réglementaire et le cycle de vie des navires, véhicules et aéronefs militaires. C’est pourquoi nous estimons que la dérogation 5.dd doit être prévue jusqu’à 2040. Justifications complémentaires en réponse à l’annexe XV - Applications militaires pour MAC et réfrigération : réponses aux limites pointées par l’annexe XV (p. 359-360) S’il est vrai que des alternatives aux réfrigérants PFAS utilisées par exemple dans le domaine naval civil où certaines contraintes similaires au domaine militaire peuvent s’appliquer, il convient de remarquer d’une part que le domaine militaire peut recourir aux solutions civiles quand cela est possible (exemple de petits programmes à durée de vie plus courte et non destinés aux opérations militaires). D’autre part, la spécificité militaire porte justement sur la présence de contraintes supplémentaires au domaine civil, en particulier concernant les contraintes de sécurité supplémentaires occasionnées soit par l’utilisation de certains systèmes de propulsion des navires de guerre, soit par les conditions d’atmosphère confinée des sous-marins, soit par une combinaison des deux. Tous domaines confondus (naval, aérien, terrestre), la projection en opérations impose des contraintes de sécurité supplémentaires en matière d’inflammabilité vis-à-vis du domaine civil. S’agissant de l’affirmation selon laquelle de nombreuses activités relatives au domaine militaire n’ont pas lieu en environnement hostile (par exemple marchés publics généraux – donc hors défense et sécurité –, hébergement des personnels et de leurs familles), cela est exact. Pour autant, il convient de remarquer les choses suivantes : - les spécificités évoquées en annexe XV, annexe E, section E.2.10 (Transports) s’appliquent essentiellement à la réfrigération « mobile », c’est-à-dire utilisée dans les porteurs militaires (navires de guerre, aéronefs, véhicules) ; - lorsque les conditions « civiles » s’appliquent (marchés publics hors défense et sécurité), les règles de droit commun sont très généralement les règles applicables ; - des conditions particulières doivent être appliquées pour le refroidissement de certains systèmes électroniques sensibles, que ce soit à terre ou dans des porteurs militaires. Pour ces systèmes et les autres utilisations de réfrigération évoquées en annexe XV, nous estimons que ce type d’usages doit pouvoir bénéficier de la dérogation générale que nous demandons dans la partie « Commentaires généraux ». Concernant les standards spécifiquement développés pour les militaires pour lesquels l’annexe E (p. 359) indique un manque d’informations sur la manière dont ces standards affectent la possibilité de considérer des alternatives comme satisfaisantes : ces standards militaires traduisent l’exigence des meilleures performances techniques pour les système d’armes, que ce soit en termes de poids, de vitesse, de puissance, de robustesse des matériaux, et aussi de rapidité d’extinction du feu, de sécurité des personnels en milieu confiné, etc. En effet, l’objectif in fine consiste à assurer la survie de nos forces armées face à des ennemis qui ne sont pas soumis aux mêmes règles que les nôtres. Les standards civils n’intègrent pas, pour leur part, le besoin d’une supériorité stratégique comme contrainte. - Résumé de l’évaluation des coûts et bénéfices - Applications militaires pour MAC et réfrigération : éléments de réponse aux informations demandées par l’annexe XV (p. 385-387) Le dossier Annexe XV demande des éléments concernant le type d’applications (« range of applications ») où cette dérogation sur les réfrigérants et MAC pour les « véhicules » militaires serait nécessaire ; en réponse, vous trouverez ci-dessous une liste non exhaustive : - Domaine naval (bâtiments de surface et sous-marins) : réfrigération des vivres embarqués, climatisation des locaux opérationnels, des locaux de vie et des installations techniques, dont les installations de propulsion ; - Domaine aéronautique : réfrigération des systèmes électroniques ; - Domaine terrestre : climatisation des véhicules. Principales autres dérogations potentielles impactant indirectement les usages défense Par ailleurs, bien qu’elles ne concernent pas spécifiquement les équipements militaires, le Ministère des Armées trouve un intérêt aux dérogations potentielles suivantes, dans la mesure où les composants, équipements, ingrédients ou applications visés font partie intégrante des équipements de défense: - 5.ee (procédé de fabrication des semiconducteurs) ; - 6.o (applications liées à la sécurité des véhicules de transport) ; Les dérogations potentielles concernant les dispositifs médicaux et l’impression 3D, si elles se justifient, sont également utiles. En effet, ces applications peuvent être utilisées par les personnels soignants des Armées d’une part et dans la fabrication de pièces de rechange de matériels militaires d’autre part. |
| Answer to specific info request 8:  Transports L’un des substituts potentiels des halons pour les extincteurs portatifs dans l’aéronautique est la substance 2-BTP. Cette substance est un PFAS et pourrait être utilisée pour les avions de mission de l’Armée de l’air. Des années de recherche ayant été investies par des industriels de l’aéronautique, la recherche d’alternatives au 2-BTP ne semble pas une option économiquement viable ni pratiquement réalisable dans les délais prévus de longue date pour les utilisations critiques de halons dans le règlement (CE) n° 1005/2009 sur les substances appauvrissant la couche d’ozone. La révision en cours de ce règlement ne prévoit d’ailleurs pas de modifier les échéances d’utilisations critiques de halons. Autres équipements et consommables des forces armées ayant recours aux PFAS En complément des usages des PFAS énumérés en partie 6 et 7, les usages suivants, notamment, ont été recensés par le Ministère des Armées (liste non exhaustive). Ces usages sont soit déjà mentionnés par le dossier Annexe XV, soit sont a priori moins spécifiques à la défense que ceux mentionnés en partie 6. Ces usages restent pour autant importants pour les matériels de défense. Non fluoropolymères - Agents de nettoyage / solvants pour les aéronefs militaires, - Système anti-incendie de véhicules de l’Armée de Terre (dérogation 5.m) - Equipements de protection individuelle, textiles de filtration et textiles de certains véhicules de l’Armée de Terre pour la protection des forces armées contre le risque NRBC (non couvert par une dérogation, sauf textiles de filtration et média de séparation) ; Fluoropolymères - Traitement de surface traité au PTFE pour les armes ; o pour ce type de traitement, aucune dérogation n’est prévue par le projet de restriction. Or il convient de rappeler que ce type de traitement constitue une alternative au chromage dur disponible commercialement, le trioxyde de chrome étant soumis au régime d’autorisation. Le PTFE dans ce traitement de surface permet de diminuer le coefficient de friction conférant à la pièce traitée une bonne résistance à l’usure et à la corrosion. - PTFE dans les colles, adhésifs et mastics de différents équipements militaires du domaine munitionnaire, aéronautique, terrestre et naval ; - Joints en fluoropolymères utilisés dans de nombreux systèmes d’armes, au-delà des munitions. Par exemple dans les avions de chasse, les bâtiments de surface ; - Revêtements tribologiques ; - Résistance aux radiations. Au global, cette liste d’usages de PFAS en complément des usages énumérés en partie 6 – même si là encore elle ne peut être ni exhaustive ni très précise en raison de la sensibilité des informations – renforce le constat d’une utilisation généralisée des PFAS dans les systèmes d’armes, et la nécessité de prendre en compte les impacts socio-économiques du projet de restriction sur le secteur de la défense. |

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| 9540 | Date:  2023/09/25 21:29  Content:  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  International NGO  Org. name:  European Federation of Allergy and Airways Diseases Patients' Associations  Org. country:  Belgium  Attachment: | General Comments:  EFA appreciates ECHA’s ongoing evaluation of a proposal from several Member States on wide-ranging restrictions on the manufacture and use of PFAS (per- and polyfluoroalkyl substances) in the EU. The proposal aims to address risks to the environment and public health posed by PFAS-containing applications and products. The scope of the proposal looks at restricting a category of PFAS, hydrofluorocarbons (HFCs), which are used in chronic respiratory disease reliever medication.  Asthma and COPD inhaled medication and PFAS  Asthma affects 30 million children and adults under 45 years of age in Europe and it is estimated that COPD affects 10% of the population in Europe.  Inhaled medicines are the most used medicines in respiratory care in Europe and worldwide. In 2021, metered dosed inhalers (MDIs) accounted for 76% of all inhalers used in Europe, and 78% of those used globally. Most MDI medicines available today contain PFAS and fall within the scope of the restriction proposal by ECHA.  Authorised by the European Medicines Agency (EMA), these MDIs are lifesaving medications where the PFAS-HFCs acts as a propellant to push and drive the medicine into the airways, effortlessly for the patient. These inhalers are considered worldwide critical medicines to treat the obstruction of the airways.  The International Pharmaceutical Aerosol Consortium (IPAC) reports that there are only two HFCs currently approved by EMA. To reduce the carbon footprint of these propellants, there are two new gases under development for inhaled medical use. However, one of these upcoming solutions falls under the scope of the current proposal for restriction of PFAS, leaving only one future HFC option as valid to transition the current PFAS based MDI portfolio. As the industry works to consolidate the effective use of the two alternatives, regulators have started to discuss the data needed to submit for them approval. The EMA has recently launched a consultation on the data requirements to approve HFC as excipients.  Given the uncertainties on the readiness of the products, and the scarce options, EFA recommends ECHA to consider avoiding any situation in which there would not be an alternative HFC for medical use. Having only one HFC option for inhaled medical use; would theoretically lead to higher raw material dependence, supply chain fragility and therefore, more vulnerability to shortages and underserved patients. Any restriction to PFAS for medical use should balance vulnerable people’s needs and pollution reduction, while avoiding that a basic excipient becomes a global monopolised commodity. |
| Answer to specific info request 6:  Health and social impacts of the PFAS restriction The HFCs under the ECHAs restriction proposal are also under scrutiny by the EU co-legislators reviewing since 2020 the F-Gases Regulation 517/2014. As in those discussions, it is alarming to see the limited scientific evidence available on the (unintended) consequences the transitioning of medication could have on people, especially the respiratory patients concerned. While EFA works unstintingly to advocate for healthier environments and the reduction of harmful exposure to environmental pollution impacting allergy and respiratory health, we invite EU regulatory agencies like ECHA to give due consideration to the potential unintended consequences these policies might have on human health, patients’ symptoms and lives. In particular: • Economic transition for patients: innovation towards less polluting medicines requires investment in research and development, medicine authorisation procedures, and market placement. This investment should not become a cost and burden to be carried by patients. • Clinical transition for patients: any restrictions and legislation affecting basic medication and treatment options would need to be thoroughly discussed with the respiratory disease community, especially medical societies and patient groups. Moreover, any major change in medication like the one proposed by this draft restriction entails sensitive health decisions that can have unintended consequences for patients (i.e. from individual stockpiling to respiratory exacerbations, even death). Finally, asthma and COPD inhalers cannot and should not be changed overnight, even less so when they are administered through a device that requires patient education and adequate inhalation technique to be used. • Global transition for patients across borders: Asthma and COPD are global diseases with an enormous burden in developing countries. According to the Global Initiative for Asthma (GINA), too rapid implementation of these restrictions would adversely affect the lives of many people worldwide – especially in low- to middle-income countries, which account for 96% of asthma deaths–. EFA is concerned about the impact the ECHA restriction proposal can have on access to healthcare and basic treatments in third countries, especially among the poorest populations. • Information transition for patients: people with asthma and COPD have the right to be informed about issues affecting their medication. This right includes information about the composition of their medicine, the environmental footprint of their treatment and its presentation, as well as how to dispose of it. Informative campaigns addressing their questions will be necessary to ensure a successful transition for all. |
| Answer to specific info request 7:  PFAS restriction: Opportunity for better lung health As patient representatives, EFA is a strong supporter of a health-in-all-policies approach. This perspective entails that changes in this medication could also be achieved through positive, rather than restrictive, EU action. Healthcare professionals are also urging to focus on “optimal treatment” when considering policies affecting people and the planet. It is well documented how there is currently an overuse of rescue medication among chronic respiratory patients, as well as specific challenges such as lack of adherence and health literacy, patients treating only symptoms, no support to patients’ self-management, lack of alternatives available for certain vulnerable groups, or even reimbursement considerations. This ECHA restriction proposal is therefore an opportunity to look at the bigger picture around inhaler use in Europe, and further address the health needs, way beyond the environmental needs, to reduce PFAS-based MDI use in Europe, by analysing issues such as: - the application of clinical guidelines for asthma and COPD at international, European, and national levels; - patients’ rights, needs and treatment choices: patients are part of the solution to reduce pollution from medicines, not the problem; - personalised medicine and alternative medicine development and affordability. All the above-mentioned aspects are necessary to scale down the use of PFAS-based MDIs to the strictly necessary circumstances. |

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| 9541 | Date:  2023/09/25 21:30  Content:  Scope or restriction option analysis  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Integer  Org. country:  United States of America  Attachment: | General Comments:  Integer manufactures complete medical devices as well as medical device components for many of the largest medical device companies in the world. Integer also manufactures batteries ranging from small implantable medical batteries to large industrial lithium batteries. Fluoropolymers such as PTFE, FEP, ETFE, ePTFE, and PVDF are all integral materials across our product portfolio. Integer, as well as the medical device and battery sectors as a whole, will be heavily impacted by a restriction of PFAS that includes fluoropolymers. Therefore, Integer would like to submit the following commentary on the proposed PFAS Restriction.  Our first request would be that fluoropolymers are excluded from the scope of the restriction. Fluoropolymers have a range of properties that make them extremely beneficial to society and these materials have become ubiquitous. They are extremely inert, highly chemical resistant, nearly frictionless, and very biocompatible, which is why they play a major role in our medical devices. Fluoropolymers are also a vital constituent in our battery and capacitor products. There are numerous examples where fluoropolymers play important roles in the fit, form, function and/or even safety of these products. A restriction on fluoropolymers will have far-reaching impacts on society that could set back quality of life improvements not only on medical devices, but also on medical procedures for many years or even decades. Fluoropolymers are undeniably useful and are arguably the safest of all PFAS, so some consideration should be made for exempting them from the broader PFAS restriction.  Additionally, it should be noted that both waste medical devices and waste battery products are regulated under other EU regulations. These regulations could be amended to ensure that resulting fluoropolymer waste is properly disposed of. For example, medical device waste is biohazardous and is often sterilized by incineration. The current regulations could be expanded to ensure fluoropolymers in medical devices are fully incinerated before disposal as well. Similar emission laws could be placed on fluoropolymer manufacturers to limit PFAS emissions during production. This sort of approach would allow the full benefit of fluoropolymers to continue in certain products while ensuring PFAS emissions to the environment are minimized.  If fluoropolymers must be included in the scope of the PFAS regulation, then Integer requests that our products utilizing fluoropolymers be provided derogations. Fluoropolymers are utilized in our devices because their unique characteristics are fundamental to their function. There are no other materials that we are aware of that could be considered direct alternatives for most of our fluoropolymer uses. Finding and employing alternatives, if even possible, will take many years due to the amount of testing and approvals required in the medical device industry. Therefore, Integer requests derogations of the longest term for all of our products listed below:  IMPLANTABLE MEDICAL DEVICES - Stents - Hernia meshes - Implantable batteries - Implantable Pulse Generators (IPG’s) and components - Leads - Feedthroughs  INVASIVE MEDICAL DEVICES - Guidewires - Introducers - Catheters and other medical tubing - Hypodermic tubing / Hypotubes - Mandrels - Other associated instruments and tools  BATTERIES AND CAPACITORS - Lithium primary medical batteries - Lithium primary industrial batteries - Capacitor cells and packs  Many of our medical devices use components made directly of fluoropolymers, but fluoropolymer coatings are also very common. Often metals in medical devices are coated with a fluoropolymer layer to reduce friction. For example, a guidewire coated in PTFE is less likely to cause damage to a patient’s interior artery wall compared to an uncoated wire. For similar reasons, hypodermic tubes, introducers, mandrels, and other instruments and tools are often coated to improve functionality and patient safety. A large group derogation for “coated medical devices” would be much appreciated and would ensure all of these life-saving, coated medical devices can continue to be produced while alternative materials are explored.  It was noted that a derogation for implantable medical devices was already included in the proposal. This covers many of our products, however, hernia meshes was specifically excluded from this derogation description. Integer would like for this exclusion from the derogation to be reconsidered as fluoropolymers play a valuable role in implantable meshes. Making implantable meshes with fluoropolymers helps prevent body tissues from adhering to the mesh device which can result in tearing. Since fluoropolymers can be crucial to the safe use of these devices, they should be included in the implantable devices derogation.  Lithium primary batteries should also be provided a derogation. Integer’s position on this is in alignment with RECHARGE. Fluoropolymers are used as electrode binder materials within all of Integer’s industrial lithium batteries. Binder materials are important in the function and manufacturability of these batteries, and fluoropolymers are ideal due to their mechanical, thermal, and dispersive properties as well as their electrochemical stability. These materials will not be easy to replace, and time will be required to explore new chemistries. The modern world is dependent on batteries, and fluoropolymers have aided in their advancement. Our large industrial batteries are heavily used by the oil and gas industry, the military, and in environmental surveying equipment. A derogation is needed to ensure these lithium batteries are not sorely impacted.  In summary, Integer believes that fluoropolymers should be excluded from the scope of the PFAS restriction. They present less risk to the environment and human health than non-polymer PFAS while also being the most beneficial to society. The medical device and battery products discussed in this commentary depend on these materials. Integer requests that our use of fluoropolymers in our medical device and battery products be provided derogations to ensure sufficient transition times to find and implement alternatives. |
| Answer to specific info request 1:  Integer’s commentary applies to our medical device and battery products that we manufacture. These would pertain to the “Medical Devices” and “Energy” sectors listed in Table 9 of Annex XV. We would like to provide additional information on some sub-sectors up for derogation reconsideration as well as propose new sub-sectors be included in the derogations. Our comments include specific fluoropolymer use and function within these products as well as a discussion on the feasibility of alternatives. Also included is commentary on disposal of these products. Our comments apply to these specific sectors and uses: Medical devices: - Implantable medical devices, specifically hernia meshes - Other coating applications, with specific product listing. Energy: - Lithium primary batteries. |
| Answer to specific info request 3:  Medical devices, once used, are considered biohazardous waste and disposal of such products is already regulated. The waste must be sterilized before disposal to remove infectious pathogens and is often incinerated to achieve this. In addition to destroying biohazardous pathogens, incineration has shown to be an effective method of destroying fluoropolymers like PTFE as well. A 2019 study released in Chemosphere by K. Aleksandrov et al. states that PTFE can be transformed into hydrofluoric acid through PTFE combustion. Carbon tetrafluoride, the simplest perfluorocarbon, decomposes at 1400 °C. Regulations can be implemented to ensure that all fluoropolymer-containing medical devices are incinerated before disposal to prevent PFAS from being released into the environment. Similarly, battery waste is regulated under WEE, Directive 2006/66/EC and the new European Battery Regulation. While these regulations focus on heavy metals, the scope of these regulations could be expanded to include fluoropolymer recycling or disposal requirements as well. As recommended for medical device waste, incineration could be a required method of disposal for the fluoropolymer component materials. A disposal cost will incur that could be absorbed by consumers and manufacturers, but ultimately regulating fluoropolymer waste on a per-product type basis would allow critical fluoropolymer applications to remain in use while meeting the goal of preventing PFAS emissions to the environment. |
| Answer to specific info request 6:  Lithium primary batteries should also be provided a derogation within the PFAS restriction because fluoropolymers are crucial to the function and safety of these batteries. PTFE is currently used as the electrode binder material within all of Integer’s lithium-oxyhalide batteries. Due to its unique properties, PTFE is the only known material that can be used as a binder to produce this type of battery. PTFE consists of very long polymer chains that effectively entangle the cathode material particles so that these particles become bound together without chemically reacting with the binder. PTFE is extremely chemically resistant and does not react at all with the highly oxidizing electrolyte liquids (thionyl chloride and sulfuryl chloride) over a very wide temperature range. PTFE is physically stable and does not melt or soften at the very high temperatures at which the batteries operate (up to 200°C). A binder material must meet all of these conditions in order to function safely. There are no alternative binder materials currently known that meet all the physical, chemical, and thermal requirements. Any alternative would need to be inert to highly oxidizing electrolytes and would need to remain physically unchanged through the entire operating temperature range of -55C to over +200C. If these parameters are not met then there is high risk that the binder will decompose, releasing the cathode particles and causing very hazardous shorting within the batteries. Integer is not aware of any research being done to design alternative compositions for these battery applications. Even if alternatives did exist today, rigorous testing would need to be conducted to ensure that the new binder material would remain physically and chemically unchanged under the conditions in which these batteries operate. Testing would need to be conducted over the wide operating temperature range and the battery products would need to undergo shock and vibration testing. More importantly, some of these batteries remain in use for over 10 years once deployed. Testing would need to be conducted to demonstrate that the alternative binder would remain stable in the electrolytes for more than ten years. Even if a non-PFAS binder material existed today, it would require the longest derogation duration to prove feasibility and safety of these products. Using an alternative material that has not been thoroughly tested could severely impact the performance of the batteries. And when dealing with such high-energy batteries, battery failures can possibly lead to severe injuries or even death. Therefore, a derogation is requested for our lithium primary battery products to ensure new designs are implemented as safely as possible. Other missing uses Integer would like to submit are for specific product types listed below that we manufacture using fluoropolymer materials. These product types were not mentioned specifically within the proposed restriction, but fluoropolymers are essential to their function and derogations should be considered. However, the typical application of fluoropolymers for these devices is as a coating and would fall under the “other coating applications” sub-use derogation. Therefore, further information is provided in the next section covering derogations marked for reconsideration. - Guidewires - Introducers - Hypodermic tubing / Hypotubes - Mandrels - Other associated instruments and tools |
| Answer to specific info request 7:  Hernia meshes was specifically excluded from implantable devices derogation description and marked for reconsideration. Integer would like for this exclusion from the derogation to be reinstated because fluoropolymers play a valuable role in implantable meshes. PTFE, ePTFE, irradiated PTFE, FEP, and PVDF are the common fluoropolymers used in hernia meshes. Lightweight meshes have been used for internal repairs for decades now and different materials have shown to have various inherent complications. Polypropylene and polyester meshes have a low risk of infection, however, these have a high risk of adhesion. In contrast, fluoropolymers, while having a higher risk of infection, have a very low risk of adhesion formation and can be utilized to mitigate this particular negative outcome. Depending on the conditions and location of the repair, a surgeon may often choose one material over another. Many modern meshes are actually composites incorporating multiple polymers with the aim to leverage the benefit of each material. Since fluoropolymers can be crucial to reducing adhesion risks in these vital medical devices, they should be included in the implantable devices derogation to ensure sufficient time to explore alternatives. In stark contrast to many non-polymer PFAS which are known to be hazardous, fluoropolymers like PTFE are extremely biocompatible and are intentionally introduced into the body regularly through medical devices. Integer manufactures a plethora of medical devices, and a portion of our devices get coated with fluoropolymers to attain a set of desired properties. For example, a guidewire coated in PTFE is less likely to cause damage to a patient’s interior artery wall compared to an uncoated wire. For similar reasons, hypodermic tubes, introducers, mandrels, and other instruments and tools are often coated with fluoropolymers to improve functionality and patient safety. Integer therefore highly encourages that derogations are reconsidered and granted for all coating applications within medical devices. Many desirable properties for medical devices are present in fluoropolymers like PTFE, PFA, and ePTFE. Some of these attributes of fluoropolymers is low friction, chemical resistance, temperature resistance, flexibility, and biocompatibility. A table comparing various polymers for these characteristics can be seen in the attached letter. There are polymers like PEEK, silicone, and polyurethane that exhibit some of these properties, however, most all of these desirable traits are present in the fluoropolymer materials being used. When considering alternatives, the Appendix to Annex E.2 lists many materials as alternatives to fluoropolymers for medical devices. Integer’s cognizant team has reviewed the list and decided to comment on the list of “alternatives” identified, specifically for the medical devices tab. Comments for each particular material is noted in the table at the end of the attached letter. To summarize, many materials listed are simply not suitable substitutes for the particular applications in which fluoropolymers are currently utilized within our medical devices. When considering the time required to implement alternatives, the qualification/validation for any alternative material could only start once a suitable substitute is identified. Identifying a substitute and determining its feasibility could take from 18 up to 24 months; lab sample review, pre-feasibility and feasibility studies would need to be executed through each iteration (rarely the first selection works as a “drop-in” substitute). Once the appropriate substitute is chosen, validation activities include Process Characterization, Operational Qualification, Product Qualification need to be executed, extending the timeline for another 12-18 months. Once Integer has validated a replacement, then our customers need to perform their own qualifications and submit regulatory approvals, adding 18-24 more months to the project timeline; worst case scenario you are looking at ~72 months (6 years) from beginning to end to have a suitable qualified and regulatory approved substitute material. Additionally, switching to a new material/process/technique would make Integer equipment/investment redundant or obsolete and would also results in more expenditure and, if new equipment needs to be introduced, Installation Qualification (IQ) and Software Validation (if applicable) would be necessary, adding another ~3-6 months to the effort. Integer has five manufacturing sites that perform fluoropolymer coatings by different techniques: Reel-to-Reel, Electrostatic Spray, Dipping and Film Casting; these capabilities mean a multi-million USD investment not only in equipment but also in facilities, utilities, manpower and resources. Two of these coating facilities manufacture guidewires within the EU and would be severely impacted by a ban on these types of coatings. For guidewires in particular, coating with PTFE is standard practice and these medical devices are not currently covered by an existing derogation. A derogation group for other coating application is needed to ensure that these life-saving medical devices can continue to be produced while alternative materials are explored. |

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| 9542 | Date:  2023/09/25 21:35  Content:  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Injecto Group A/S  Org. country:  Denmark  Attachment:  <redacted>  Privacy statement:  No confidential information should be included, mainly due to protection of our commercial interests and intellectual properties. | General Comments:  We kindly mention that the following comments are from Section 3-6 in our letter mentioned below and that some of the mentioned link can be found in attached files to this letter just like the letter also contain references to other sources mentioned below.  INTRODUCTION TO MARKET FOR PRE-FILLABLE INJECTION DEVICES  A pre-fillable injection device, known from the fifties, is a combination product which function as primary packaging for the drug product and as an administration device of the drug product. These kinds of devices are specially designed to minimise the need for overfill, eliminate the withdrawal step (during aspiration) and deliver the drug product directly to the patient, resulting in a more accurate drug dose with less exposure to needle injuries.  The use of pre-filled injection devices over the traditional vial and disposable syringe combination provides substantial economic benefits for clinical settings, cf. the attached Memo “Making the case for Pre-filled syringes” published on the following link: https://www.eahp.eu/sites/default/files/2spd-033\_1.pdf  The components of a pre-fillable injection device play an essential role in maintaining the stability of the drug product, avoiding contamination and handling problems. Containers, plungers, needle shields, plunger rods, etc. are components of the syringe.  Prefilled injection devices are used for packaging injectable drug products and diluents. The drug products packaged in prefilled syringes are vaccines, blood stimulants, therapeutic proteins, erythropoietins, interferons, mAbs and new biologics. Since the components, especially the plunger, are constantly in contact with the pharma, drug products from the fill and closure until the administration, the plunger plays a crucial role in the product's exposure to leachables and extractables over the storage time.  The European market for pre-fillable injection devices is comparatively more mature than the US market, cf. the extract from Fortune Business Insight’s survey of the market for pre-filled published on the following link: https://www.fortunebusinessinsights.com/industry-reports/prefilled-syringes-market-101946  INTRODUCTION TO THE MARKET FOR VIALS  Currently the most utilised primary packaging for drug products are vials, where the majority of container closure systems is also based on (halogenated) butyl rubber stopper.  Although, there is air (headspace) between the drug product and the stopper, the drug product may have direct contact with the stopper over the shelf life of the product. Therefore vial stoppers are equally often coated by the same PFAS variants as the plungers used as closures in the pre-fillable injection devices.  INTRODUCTION TO THE CURRENT YEARLY CONSUMPTION OF COATED PLUNGERS AND STOPPERS AND THE EXPECTED GROWTH RATE  Based on a brief estimate coated plungers in pre-fillable injection devices are only used in approximately 20 % of the current yearly consumption of approximately 6.7bn units with a compounded growth rate of more than 10%, cf. an extract from the attached market survey from Smithers back from 2015.  Coated stoppers for vials are estimated to be used in approximately 10 % of the current yearly consumption of approximately 15-20bn units, cf. Reuters with a compounded annual growth rate of 6-7%, cf. the extract from a report about the “Sterile Rubber Stopper Market” published on the following link: https://www.futuremarketinsights.com/reports/sterile-rubber-stopper-market [5.3) With an increase in new sensitive biologics, due to a trend towards high concentrations and larger and more complex molecules, it is likely to assume that the use of the coated plungers and stoppers will increase exponentially over the next decade and hence the exposure to PFAS unless restricted. [5.4] There are currently more than 20,000 drug products in the global pharmaceutical pipeline, where approximately 44% are biotech drug products and 61% of those are parenteral drug products for injection, cf. page 5 in the attached White Paper from 2022 (Attachment 08) published on the following link: https://pages.pharmaintelligence.informa.com/rdreview?utm\_source=RDReview2022&utm\_medium=whitepaper&utm\_id=2296624620) These candidates will most likely be delivered in a primary packaging with a coated plunger or stopper component.  PLUNGERS AND STOPPERS WITH COATING  Long before the consequences of PFASs was known and taken seriously by law makers, some of the global leading suppliers of plungers introduced the coated plungers for pre-fillable injection devices. These coatings made of polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), Polychlorotrifluoroethylene (PCTFE) or similar fluoropolymer-based variations should contribute to a more secure solution since the risk of adverse extractable and leachable substances, including antioxidants, plasticizers, dyes and metal catalysts, and polymer and degradation products, from the underlying rubber was significantly reduced. However, it should be noted that the fluoropolymer coatings are also known as a potential leachable, thereby introducing PFASs directly into the human or animal circulatory system, dermis, muscular, or mucosa tissue.  Coatings are mainly used on plungers for pre-fillable injection devices and on vial stoppers used as primary packaging of advanced drug products, such as biologics, where the leachable substances may be considered a health hazard due to their inherent toxicological properties. For some drug products it is a nice-to-have and for other a-need-to-have due to their acute risk of adversely reacting with the leachable substances from the rubber formulation.  Additionally, coatings on the plungers and stoppers, in combination with silicone oil, are also used to ease the processability and to reduce operating forces (friction) caused by the adhesive behaviour of rubber. Both the coatings and silicone oil are extrinsic substances in the drug products, known to cause particulates which consequently risk forming protein aggregations leading to lowered stability, lowered efficacy and can lead to immunogenic responses.  To give an impression of some of the most relevant products in the market reference is made to the following: \* Novapure from West Pharmaceutical, cf. the attached Brochure published on the following link: https://www.westpharma.com/es-es/blog/2022/june/novapure-components-for-lifecycle-of-injectable-drug-product \* Neoflex from Datwyler, cf. the attached Brochure (Attachment 10) published on the following link: https://datwyler.com/files/pages/data/downloads/sealing-solutions-prefilled-syringes/873a71fbc4-1670401504/datwyler.com\_sealing-solutions\_prefilled-syringes.en.pdf \* Premium Coat from Aptar, cf. the attached Brochure (Attachment 11) published on the following link: https://www.aptar.com/wp-content/uploads/2022/10/Aptar-Pharma-PremiumCoat-Coated-vial-stopper-and-syringe-plunger\_Oct2022.pdf \* P101-A from Sumitomo Rubber Indutries, cf. the attached Brochure (Attachment 12) published on the following link: https://www.lonstroff.com/wp-content/uploads/2019/02/SRI\_Profile.pdf \* Improject from Gore, cf. the attached Brochure (Attachment 13) published on the following link: https://www.gore.com/system/files/2019-11/PB8759\_Rev3\_MA\_US\_SEP19-e.pdf  The coated plungers supplied in pre-fillable injection devices and stoppers for vials in Europe are mainly produced and supplied by four of the five companies mentioned above (sometimes also supplied by one of the major primary packaging providers like Becton, Dickinson and Company (BD), Schott, Stevanato Group (Ompi) or Nipro Corporation with one of the four companies as sub supplier).  According one of the new investors, Sifter (https://sifterfund.com/en/sifter-fund/), in the American company, West Pharmaceutical (https://www.westpharma.com), listed on NYSE, is the leading provider of coated rubber for pharmaceutical primary packaging, where it is mentioned that the company holds 70 % of market towards the competitors, Aptar’s and Datwyler’s 10 % and 20 %, cf. the following link: https://sifterfund.com/en/west-pharmaceutical-services-is-a-perfect-example-of-a-quality company-with-strong-entry-barriers/  Therefore, it can be concluded that there is a limited competition in the market for the coated plungers and stoppers containing PFAS, and that an American company apparently holds around 65-70 % of this market. This should be an important fact for ECHA to pay attention to when considering the issue of replacement for coated stoppers and the length of a derogation period, where this company naturally together with some of the other leading providers of plungers and stoppers with PFAS coating have a substantial interest in alleging that there are no foreseeable alternatives – not even in the future. |
| Answer to specific info request 1:  1) Medical devices (annex E.2.9) Sub-uses: Packaging of medical devices. 2) Medical devices (annex E.2.9) Sub-uses: Other Coating applications. 3) Additionally, there should be a sub-use definition for “Coating for primary pharmaceutical packaging (on vial stopper and plunger stoppers)” |
| Answer to specific info request 4:  Contrary to (halogenated) butyl rubber, the TPE materials can be recycled. |
| Answer to specific info request 6:  Coating for primary pharmaceutical packaging on vial stoppers and plunger stoppers for prefilled syringes and cartridges has not been explicitly categorized. With billions of PFAS-based coated parts being used every year, we believe this should be addressed. |
| Answer to specific info request 7:  We kindly mention that the following comments are from Section 7-9 in our letter mentioned below and that some of the mentioned links can be found in attached files to this letter - just like the letter also contains references to other sources mentioned below. IT IS POSSIBLE TO REPLACE THE COATED PLUNGERS AND STOPPER WITH PFAS IN PRE-FILLABLE INJECTION SYSTEMS AND VIALS Irrespectively of the technical possibility of replacing coated PFAS plungers for pre-fillable injection devices and coated PFAS stoppers for vials and without a detailed survey of plungers and stoppers it seems that ECHA in the restriction report has decided to treat medical devices as homonymous group rather than looking into the different product categories and potentially accepted the biased position by protagonists such as EFPIA (representing the European pharmaceutical industry) and AnimalhealthEurope (representing the European animal health industry) on use and risk of “per- and polyfluorinated alkyl substances” (PFAS) in Europe, in the light of an emerging Restriction under REACH, cf. the following link: https://www.efpia.eu/media/636866/pfas-position-\_-efpia-and-animalhealtheurope-january-2022.pdf and presumably accepted the following wrongful allegations from this link: “ETFE or PTFE film coated elastomeric components provide an effective barrier against organic and inorganic extractables and minimize interaction between the drug and the PPC. Furthermore, ETFE or PTFE film reduces absorption and adsorption of the drug product. Elastomeric PPC’s also require a lubrication to prevent stickiness during storage and processing. We could use a typical silicone lubricant, but the silicone can be a source of particles in the drug product. The ETFE or PTFE film provides a particle free lubrication and prevents or reduces the use of silicone. All of these PFAS materials are in direct contact with the drug product. As such, they are part of the drug product qualification and registration. As far as our industry is aware, there are no feasible alternatives though we continue to engage with our Supply network to identify any alternatives available in the required volume. Any replacement of a primary packaging material of medicine in the market triggers a full requalification with the relevant Health Regulators. This process would take at least five years depending upon which global market the products are sold into and would entail the following activities: \* Compatibility / Stability study – shelf-life qualification \* Extractables / Leachable assessment \* Functionality qualification \* Processability qualification \* Re-submission to health authorities” With reference to the comments above, including our reference to Aseptic Technologies’ use of TPE material for high-end stoppers for vials and our tests of our lubrigone stoppers with Top-5 pharma and biologic companies and Gerresheimer AG (second largest provider in the world of pre-fillable syringes and largest provider of vials), where our product will be in the market before the end of 2025 in pre-fillable injection devices, the allegation of lack of feasible alternatives is simply not true and it would be embarrassing if this kind of unfounded allegation against facts should determine the restriction. Moreover, it should be noted that the arguments that it would take at least five years to replace a primary packaging component simply is incoherent nonsense, substantiated by the following: Strategic aspects of change control for pharmaceutical packaging systems European Pharmaceutical Review, by Dennis Jenke (Baxter Healthcare Corporation), 20 April 2017, cf. the following link: https://www.europeanpharmaceuticalreview.com/article/77429/strategic-aspects-of-change-control-for-pharmaceutical-packaging-systems/ Abstracts: “Although there are compelling reasons to minimise changes to an approved packaging system and/or its materials of construction, it is an unfortunate reality in the pharmaceutical industry that packaging systems and their materials of construction are changed with inopportune frequency. … Change control is potentially quite different from initial registration, as a change occurs after the initial registration has been secured. A change is made to a packaging system that has already been established as being suited for use, meaning that the question to be addressed in change control is not necessarily, “is the changed packaging system suited for its intended use?”, but rather, “how does changing the packaging affect its suitability?” This distinction is important because it raises the possibility that change control testing could be less extensive than the testing required for initial registration. That is, the effort required to establish ‘relative’ suitability (i.e., no change in suitability) may be considerably less than the effort to establish ‘absolute’ suitability (i.e., that the system is suitable). … Conclusion Changes to approved/marketed packaging systems are unavoidable in the pharmaceutical industry. Such changes are managed by a process termed change control. Although the considerable variation in possible changes adds uncertainty to change control, certain aspects are straightforward to define and address.” Testing lengths required to prove drug stability, cf. European Medicines Agency (EMA) GUIDELINE ON STABILITY TESTING: STABILITY TESTING OF EXISTING ACTIVE SUBSTANCES AND RELATED FINISHED PRODUCTS London, 17 December 2003 CPMP/QWP/122/02, cf. the following extract from the following link: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-stability-testing-stability-testing-existing-active-substances-related-finished-products\_en.pdf “1.2 Scope of the guideline The guideline addresses the information to be submitted in registration applications for existing active substances and related finished products. … 2.1.4 Container Closure System … The stability studies should be conducted on the active substance packaged in a container closure system that is the same as or simulates the packaging proposed for storage and distribution. … 2.1.6 Testing Frequency … At the accelerated storage condition, a minimum of three points, including the initial and final time points (e.g., 0, 3, and 6 months), from a 6-month study is recommended. When testing at the intermediate storage condition is called for as a result of significant change at the accelerated storage condition, a minimum of four time points, including the initial and final time points (e.g., 0, 6, 9, 12 months), from a 12-month study is recommended. …” Assessment of regulatory (EMA) processing time for approval of changes Prepared by Amgros, Horizon Scanning, 1st edition, February 2018, cf. the following extract from the following link: https://amgros.dk/media/2621/navigating-the-ema\_final.pdf, where it is clearly stated that the timelines for regulatory authority’s approvals of major changes (Type II) are 9 months, however, the response time (Clock stop) of the sponsor must be considered: Comparison between EMEA and FDA (please see the following link (in pictures): https://www.google.com/search?client=safari&sca\_esv=568211807&rls=en&q=Comparison+of+regulatory+approval+times+of+EMA+and+FDA&tbm=isch&source=lnms&sa=X&ved=2ahUKEwjxhbjBkcaBAxUye6QEHWi-AKMQ0pQJegQICxAB&biw=1324&bih=839&dpr=2 Finally the companies, who are trying to protect their market position and access to the future market by wrongful allegations about that there should be no alternatives to their coated plungers and stoppers with PFAS in their additional argumentation of the time it will take to implement feasible alternatives in regulatory have not just ignored the facts mentioned in paragraphs 7.2 and 7.3 but furthermore ignored various regulatory, e.g. FDA’s acceptance of fast track. In addition to the fact that it both from a technical and regulatory point of view is possible to replace the coated plungers and stoppers with PFAS with alternatives, where our lubrigone plungers and stoppers based on the same TPE material as Aseptic Technologies’ well proven stopper solution for vials we would like to emphasize that there are the following significant advantages related to the production of plungers and stoppers made of TPE over the coated rubber plungers and stoppers with PFAS: SCALABILITY OF TPE PLUNGER PRODUCTION The rubber plunger and stopper production require multiple lengthy steps before attaining the final products, cf. the article from Renaud Janssen from Datwyler Sealing Solutions back from 2013 on the following link, https://www.rapiddirect.com/knowledge-base/ultimate-guide-to-injection-molding/, where reference is made to figure 6. Plungers and stoppers based on TPE are produced by injection moulding in a process where the raw material is melted to a liquid state, injected into high precise part-forming cavities, and cooled to regain its solid (elastomeric) state before ejecting the parts. A process cycle is typically only 20 seconds. The injection moulding process is a high-precision technique where the components are moulded into their final shape and therefore do not require additional die-trimming. Injection moulding can be performed directly in clean room according to International Standard Organisation (ISO) governed by the specification ISO 14644-1, and therefore does not require neither, washing, drying, coating or similar post-processing procedures. High performing tools for injection moulding typically have 16 or 32 cavities and are therefore capable of producing 48 to 96 units per minute. Considering a typical overall operating efficiency of 80% of the approximately 320 yearly production days, the output of a single production line can easily be (48-96 pcs x60 minutes x24 hours x322 days x80% OEE) between 17,8m to 35.6m units/year. Even considering a 5% scrap of all parts produced, substituting all coated plungers for pre-filled syringes in the current market demand could be obtained with less than 50 production lines having 32 cavities or less than 90 production lines having 16 cavities. An injection moulding tool and an injection moulding machine typically takes around 20 weeks to produce and install, and the run-in, verification and validation following Good Manufacturing Processes (GMP) according to the required quality systems governed by ISO 13485 would take around 26 weeks. Conclusively, a production capacity sufficient to let TPE plungers replace the coated plungers in plunger market could in theory be established in less than a year. Hence the needed scale-up of the TPE plunger production can simply not justify a long derogation period. In addition to the avoidance of PFAS by use of plungers and stoppers made of TPE it should be noted that there will be a lot of other benefits e.g., substantial energy savings and limiting of CO2 emissions by the injection moulding process instead of the filthy and energy consuming production of the rubber plungers and stoppers that are coated. COMMENTS TO THE SUGGESTED DEROGATION PERIOD We have with respect to the possibilities of replacement discovered that it in the restriction report has been suggested that the 12 years derogation and 18 months transition period are marked for reconsideration after consultation: “j. [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF]; k. [Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF]; l. [PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF]; m. [PTFE in ophthalmic solutions packaging until 13.5 years after EIF]; …” In this respect we and with reference to our comments above in section 6 we will emphasize the following: FIRSTLY, the alternative and fully feasible uncoated TPE material for a stopper solution has been used in several years by GlaxoSmithKline (GSK) and Aseptic Technologies SECONDLY, our co-operation and tests with some of the leading suppliers of pre-fillable systems like Gerresheimer and some of the leading pharma companies make us believe that we already in 2024 or at least before the end of 2025 have delivered our lubrigone plungers in a pre-fillable syringe. THIRDLY, our lubrigone plunger is the only true and genuine fully silicone-oil free (lubrication free) solution, which is eminent for the ophthalmic solutions mentioned in point m and hence - irrespective of the PFAS - the only right solution for eye injections and will prevail over the coated solutions. FOURTHLY, our lubrigone plunger is proven suitable for deep freezing storage, where one of the world’s leading pharma- and biotech companies have short listed our product since all coated solutions failed. It should be noted that one of the providers of the PFAS coated plungers suggested that they suddenly could remove the coating since leaching, particles and protein aggregation were no longer an issue when the product was frozen and stored at a temperature below the glass transition temperature. This “fresh” suggestion was prudently rejected by the competent pharma and biotech company. FIFTHLY, it would be troublesome if ECHA decided to rely on information from the established players in the market, who almost has a monopoly on coated plungers and stoppers and accept such a long derogation and transition period as 13,5 years in a technology driven market, where other companies have chosen a much more dynamic and responsible way by making a decision of a total stop of production and sales of products with PFASs. In this respect is referred to 3M, who was one of the US’ and the world’s leading supplier of products containing PFAS, cf. the link: https://news.3m.com/2022-12-20-3M-to-Exit-PFAS-Manufacturing-by-the-End-of-2025 SIXTHLY, it would be troublesome if ECHA gave an American company, who holds around 70 % of the coated plunger and stopper market and has based its products on a PFAS-based coating, an acceptance of an unambitiously long derogation and transition period of 13.5 years, which long period would enhance their position in the market. It is surprising that the providers of PFAS-based coated plunger and stopper solutions do not have the willingness to find alternatives and apparently have ignored (maybe deliberately turned the classical “Nelsonian Eye” to feasible alternatives) at the same time as they allege that they need a very long time – 13,5 years – to find and implement another solution. This attitude and approach stand in stark contrast to 3M and seems to be in contradiction to the dynamics in the USA where it only took the country around 8 years to land the rocket on the moon from their President’s announcement before a special joint session of the Congress on 25 May 1961. We fully appreciate the need for security and consistency in supplies of equipment for healthcare and a realistic approach to social-economic consequences and in principle do accept that a total restriction after 18 months (RO1) of coated stoppers unfortunately will not be fully acceptable. Notwithstanding the foregoing and based on the facts listed above the derogation period should, according to RO2, not be 12 years but limited to 5 years or even less. Additionally, we think that the sub-use as primary packaging of pharmaceutical parenteral drug products should be a separate distinction in the Annex XV table 9, Annex E.2.9.’ SOCIO-ECONOMIC IMPACTS Despite the substantial and constantly increasing number of coated plungers and stoppers for primary packaging for pharma and biologics used annually in Europe the total volume of PFAS consumed for these products is far less than the consumption for products in other industries and hence presumably has a less impact on pollution of the environment, e.g. the ground water. This does however not change the fact that the use of PFAS in primary packaging and medical devices can have a substantial socio-economic impact due to its effects on the health of both humans and animals, who are mostly exposed in the following stages: \* Humans during the production \* Humans and animals in their capacity of their use of pharma and/or biologics in primary packaging and medical devices in connection with the administration and after the administration \* Disposal In the foregoing respect is referred to Cost of Inaction from the Nordic Counsil of Ministers with a socioeconomic analysis of environmental and health impacts linked to exposure to PFAS, which report can be found on the following link: https://norden.diva-portal.org/smash/get/diva2:1295959/FULLTEXT01.pdf It appears from page 14 and 74 in this report that the health-related costs to society are substantial, in which connection reference is also made to the following extract from the attached short introduction, cf. the following link: http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1295959&dswid=5042 “… Findings indicate that the costs are substantial, with annual health-related costs estimated to 2.8 – 4.6 billion EUR for the Nordic countries and 52 – 84 billion EUR for all EEA countries. Overall non-health costs are estimated at 46 million – 11 billion EUR for the Nordic countries. …” The aforementioned estimated annual costs by far exceeds the commercial value for the society to protect the chemical industry and allow continued use of PFAS, where there are feasible alternatives. The risks and adverse effects of PFAS will not just impose financial burdens on the societies but furthermore allow material adverse effects on human beings and animals with lost wages for humans, lost years of life, reduced quality of life with stress, anxiety and depressions with subsequent impacts on families and communities. As stated on page 2 in the article from Berkley Life Science testing for PFAS in clinical testing, which article was published on https://berkleyls.com/news/pfas-forever-chemicals-medical-life-sciences-products/, where testing methods for PFAS continue to improve and research on health impacts constantly grows should make the awareness of avoiding PFAS in primary packaging high and contribute to an efficient restriction within a limited number of years. |

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| 9543 | Date:  2023/09/25 21:42  Content:  Scope or restriction option analysis  Description of analytical methods  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Solenis Technologies Germany GmbH  Org. country:  Germany  Attachment: | General Comments:  On behalf of Solenis, I would like to highlight and bring attention to the analytical method chosen to analyze PFAS under proposed Annex XV restriction. Wrong choice of methodology leads to the risk of false positive result of articles where inorganic fluorine is present. In our opinion, proposed restriction will raise a disproportional burden on the manufacturers of such materials making an equal sign between intentionally added PFAS and presence of inorganic fluorine. |
| Answer to specific info request 1:  Food contact materials and packaging (Annex E.2.3.): -Industrial food and feed production -Paper & board packaging -Other packaging applications |
| Answer to specific info request 10:  To test compliance with the ban of PFAS in paper and board food contact materials, the total organic fluorine (TOF) method was developed for the Danish authorities. The TOF method screens for just fluorine by combustion of the total sample, in which any fluorinated compound is converted to hydrogen fluoride, followed the absorption of HF into an aqueous media and the amount of fluorine is measured by ion chromatography. The TOF method is a non-specific method, which means it can’t distinguish organic fluoride (OF) from inorganic fluoride (IF), so the separation of the two fraction is needed. The method is quite simple, and the cost is rather low, which makes it suitable for compliance testing and enforcement. Since this method measures all organic fluorides in a sample, it can be considered as an accepted proxy for the total PFAS content for paper and cardboard, as other fluorinated compounds than PFAS, like for example antibiotics, are rarely used in food packaging. Therefore, the Danish authorities has set an indicator value of 20 mg/kg total organic fluorine measured as a guideline to differentiate between intentionally added PFAS and background levels due to environmental contamination, because PFAS residues are already persistently present in the environment. However, there are two disadvantages to this TOF method. One, high chloride content and earth alkali elements may cause interference, but most importantly, the extraction of inorganic fluoride and method thereof used is crucial for the accuracy of the results. Therefore, Solenis analytical department in Wilmington suggested to use nuclear magnetic resonance spectroscopy or NMR. This analytic technique observes the local magnetic fields around atomic nuclei. The sample is placed in a strong magnetic field, a radio wave at a certain frequency is radiated at the sample and a signal is produced by excitation of another radio wave from the nuclei. The weak intramolecular magnetic field around an atom (caused by its surroundings) in a molecule will change the frequency of this waves and thus this so-called “chemical shift” gives details of the electronic structure of a molecule and its functional groups. Detailed description of the work done by the Solenis researchers can be found in the attached paper. |

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| 9544 | Date:  2023/09/25 21:42  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Danish Waste and Resource Industry  Org. country:  Denmark | General Comments:  - |
| Answer to specific info request 4:  The Danish Waste and Resource Industry (ARI) would like to bring the market for reuse and recycling across sectors, but with special focus on reuse and recycling of building waste, into consideration. The report does not seem to cover the reuse and recycling market to any extend. If we want an effective market for reuse and recycling of materials, then we need new regulation to consider the impact not only on the production and use of products made from virgin materials, but also consider the impact on reuse and recycling. Building waste accounts for about 40 % of the entire waste stream in the EU. If the framework around reuse and recycling of building waste is not clear and transparent, then reuse and recycling will stop. ARI would like to propose that the contend of PFASs in reused and recycled materials should be examined, before reused and recycled material should be prohibited by the proposal. If reused and recycled material are to be included in the proposal, it is vitally important that the standards and procedures around how to determine if a recycled material is contaminated or not and thereby restricted or not is in place no later than the restriction itself. |

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| 9545 | Date:  2023/09/25 21:46  Content:  Scope or restriction option analysis  Hazard or exposure  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Trade union  Org. name:  KSP NSZZ "Solidarność" (Fire Brigade Section of Independent Self-Governing Trade Union "Solidarity")  Org. country:  Poland  Attachment: | General Comments:  KSP NSZZ "Solidarność" (Fire Brigade Section of Independent Self-Governing Trade Union "Solidarity") requests that PFAS agents not be excluded from the ban on use for firefighters' personal protective equipment, due to emerging information about their harmfulness to human health. Alternatively, the KSP NSZZ "Solidarność" (Fire Brigade Section of Independent Self-Governing Trade Union "Solidarity") takes the position that any exclusion from the ban on use should be as short as possible, as the best possible protection of firefighters' health should be sought. The presented analyses of the use of PFAS agents, focusing on various aspects of the matter (socioeconomic impact, cost burden on the environment, etc.) ignore one important factor in the work of firefighters: long-term, regular contact with protective measures over several decades. Firefighters are in an occupational group at particular risk of contracting cancer due to their work environment (IARC WHO 2022, Monograph 132) and shift work (IARC WHO 2010, Monograph 98).  Citing Appendix E of Report XV: - “Information from one manufacturer of PPE suggested that an alternative weave construction could replace existing PFAS-based coatings in some PPE.” - “There is sufficiently strong evidence that a derogation of PFAS use in PPE (either for 5 or 12 years) will cause substantial additional emissions which are below additional emissions under (worst-case) scenarios.” - “Products, for which a full ban of PFASs is likely to lead to products not being available to EU customers as a result of technical feasibility considerations include, for example, Category III PPE for the protection against liquid and gaseous chemicals, including aerosols and solid particles, and microorganisms, and PPE for firefighting activities. A full ban of PFAS would also prevent maintenance, i.e. re-impregnation, of Category III workwear already in use. For these products, alternatives to PFASs are not able to provide the required functionalities at the level that is necessary to reach the requirements set out in EU legislation according to the assessment of the Dossier Submitters presented in Section E.2.2.2. As the provision of products of lower quality (below the set standard) is not acceptable for such products, a complete restriction of PFASs would actually result in the complete unavailability of suitable PPE for these types instead of changes to the quality of PPE on the market.” - “A ban with a transition period of 18 months and a 12-year derogation is proposed for: Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c); Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m); and Impregnation agents for re-impregnating of articles referred to above.”  In addition, consideration should be given to whether a more effective way to protect the health of firefighters would be to amend EN 469 to reduce the requirements for clothing water repellency and chemical resistance. In the firefighting community, there is a belief that the water repellency of special clothing is not enough to justify such high requirements for protective clothing that would justify the use of PFAS substances with all their negative effects. In addition, special clothing is used for protection against chemicals and therefore the requirement for chemical resistance of clothing intended for fighting fires in buildings may not be justified in view of the negative effects of PFAS substances on the health of the wearer and the environment. The same observation applies to firefighter gloves. |

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| 9546 | Date:  2023/09/25 21:46  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Sweden  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  Protection of technical details on uses related to defense products. | General Comments:  Saab serve the global market with world-leading products, services and solutions from military defense to civil security. Our products are sold to over 100 countries and we currently operate in over 30 countries worldwide. Saab systems and products are integrated in complex platforms (vehicles, ships, submarines, aircrafts, sensor and communication systems, weapon and warhead systems) using a wide range of technologies and using a many tier global supply chain contributing sub-systems and parts. Saab products are highly technical and extremely complex. Aerospace and Defense (A&D) products are subjected to some of the most aggressive environments around the world. They must operate successfully in extremes, not limited to altitude, temperature, pressure, and precipitation, while having to fulfil the highest possible technical reliability and safety requirements. Most applications in Saab products (including products for civil Safety & Security), systems, production and test equipment are dependent of PFAS to provide crucial functions to secure safety, durability and reliability and long operating lifetime. Legislation restricting substances should not be implemented without a differentiated consideration of their uses and the consequences. A risk-based and substance-based approach should be used for PFAS. We consider the recommended proposals for restriction of all PFAS, regardless of their toxicity and risk profile disproportionate. Moreover, the proposed total ban would risk creating technical barriers to international trade. Use of PFAS must remain possible as long as there is no full-scale availability of suitable and technically developed substitutes. Saab therefore proposes the following general and specific changes: • Exclude fluoropolymers without relevant risk from the scope of the restriction (and the precursor PFAS substances necessary for their manufacture). • Include a sector-wide derogation for A&D and civil Safety & Security uses of non-polymeric PFAS with a review clause upon the expiry of the derogation period to allow for an extension depending on the availability of suitable alternatives. • A clearly defined procedure for the application, review, and extension of derogations is crucial, especially in the case of a broad restriction on previously non-declarable substances. The derogations currently envisaged are insufficient and do not take into account the relevance of PFAS for a wide range of uses and ongoing innovations in the technology industry. • Exclude certified/approved spare parts and legacy spare parts containing PFAS needed for maintenance, repair, operation of existing products. • Include a general derogation for products that have already been placed on the market for the first time. Otherwise, they cannot be resold, refurbished, remanufactured or further processed and placed on the market again. • To avoid duplicated regulation, clarify the interface with the EU F-Gas and Ozone Regulation and ensure that restrictions and derogations are aligned. Alternatives need to be in place for refrigerants and fire suppression systems before any restriction for these uses entry into force.  Detailed information is available in attached Saab documents and in the European Aerospace, Security and Defence Industries input to this consultation, (Reference number: 9639d9a5-5f72-43ee-a9f8-6a8e23a3e149). |
| Answer to specific info request 1:  Information is provided in the attachments |
| Answer to specific info request 2:  Information is provided in the attachments |
| Answer to specific info request 3:  Information is provided in the attachments |
| Answer to specific info request 4:  Information is provided in the attachments |
| Answer to specific info request 6:  Information is provided in the attachments |
| Answer to specific info request 7:  Information is provided in the attachments |
| Answer to specific info request 8:  Information is provided in the attachments |

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| 9547 | Date:  2023/09/25 21:49  Content:  Scope or restriction option analysis  Hazard or exposure  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  National NGO  Org. name:  Fundacja cfbt.pl (cfbt.pl Foundation)  Org. country:  Poland  Attachment: | General Comments:  The cfbt.pl Foundation requests that PFAS agents not be excluded from the ban on use for firefighters' personal protective equipment, due to emerging information about their harmfulness to human health. Alternatively, the cfbt.pl Foundation takes the position that any exclusion from the ban on use should be as short as possible, as the best possible protection of firefighters' health should be sought. The presented analyses of the use of PFAS agents, focusing on various aspects of the matter (socioeconomic impact, cost burden on the environment, etc.) ignore one important factor in the work of firefighters: long-term, regular contact with protective measures over several decades. Firefighters are in an occupational group at particular risk of contracting cancer due to their work environment (IARC WHO 2022, Monograph 132) and shift work (IARC WHO 2010, Monograph 98).  Citing Appendix E of Report XV: - “Information from one manufacturer of PPE suggested that an alternative weave construction could replace existing PFAS-based coatings in some PPE.” - “There is sufficiently strong evidence that a derogation of PFAS use in PPE (either for 5 or 12 years) will cause substantial additional emissions which are below additional emissions under (worst-case) scenarios.” - “Products, for which a full ban of PFASs is likely to lead to products not being available to EU customers as a result of technical feasibility considerations include, for example, Category III PPE for the protection against liquid and gaseous chemicals, including aerosols and solid particles, and microorganisms, and PPE for firefighting activities. A full ban of PFAS would also prevent maintenance, i.e. re-impregnation, of Category III workwear already in use. For these products, alternatives to PFASs are not able to provide the required functionalities at the level that is necessary to reach the requirements set out in EU legislation according to the assessment of the Dossier Submitters presented in Section E.2.2.2. As the provision of products of lower quality (below the set standard) is not acceptable for such products, a complete restriction of PFASs would actually result in the complete unavailability of suitable PPE for these types instead of changes to the quality of PPE on the market.” - “A ban with a transition period of 18 months and a 12-year derogation is proposed for: Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c); Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m); and Impregnation agents for re-impregnating of articles referred to above.”  In addition, consideration should be given to whether a more effective way to protect the health of firefighters would be to amend EN 469 to reduce the requirements for clothing water repellency and chemical resistance. In the firefighting community, there is a belief that the water repellency of special clothing is not enough to justify such high requirements for protective clothing that would justify the use of PFAS substances with all their negative effects. In addition, special clothing is used for protection against chemicals and therefore the requirement for chemical resistance of clothing intended for fighting fires in buildings may not be justified in view of the negative effects of PFAS substances on the health of the wearer and the environment. The same observation applies to firefighter gloves. |

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| 9548 | Date:  2023/09/25 21:50  Content:  Scope or restriction option analysis  Hazard or exposure  Information on benefits  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United States of America  Company name confidential:  Yes | General Comments:  The proposed restriction options submitted by the Member States do not provide adequate scope for all of the required time-unlimited exemptions ourselves at SDC Technologies and the ophthalmic medical device industry believes are necessary for the risk-to-benefit profile of PFAS-containing substances and articles where used in essential use item(s). This is particularly important in cases where there is no pertinent risk of exposure or environmental emission during the intended use of the essential article, and where the PFAS is used in such low quantities (trace ppb in finished article as used) that the assumed hazard is negligible. For this, SDC Technologies requests that the criteria for time-unlimited exemptions for medical devices, namely in the eyewear market, is reviewed, broadened and incorporated into the proposal.  We believe the scope of the restriction is too broad, including fluoropolymers, which exhibit vastly different properties with regards to environmental and toxicological hazards. As fluoropolymers are the most widely-used PFAS subset for medical devices (Annex A.3.10.1.17), their inclusion in the restriction proposal would cause widespread disruption to the availability of resources in the medical professions. In this sector, availability of replacements will be slow to market, as replacement chemistries that exhibit similar performance properties are improbable, and will be subject to rigorous, time-intensive accreditation procedures, causing further delay before full-scale deployment in these applications. This is true for medical ophthalmic lenses, an essential-use item as millions of EU nationals rely on these daily. The presence of PFAS at ppb level in lens coatings helps to impart scratch-resistance, dirt-repellent and anti-reflective properties that make prescription eyewear safer to wear for the user, and allows for a longer life of service. These substances are suspended in the polymerisation process of these coatings, effectively eradicating the risk of migration. SDC requests that fluoropolymers are omitted from the scope of this PFAS restriction proposal.  “Medical devices” itself is a broad sub-group of PFAS-containing substances, of which ophthalmic lenses applications have been included. PFAS-containing coatings for medical devices are used in very low levels in the article production process, and carries negligible risk and/or hazard of emission in production and intended use in comparison those medical devices with gaseous/propellant applications, where emissions are made direct to environment. SDC believes it is inappropriate for these uses to be classified under the same emission potential grouping, and further resolution should be made to better segregate emission routes with medical device applications.  The PFAS tonnage consumed in the eyewear industry contributes to a negligible fraction of the overall medical devices estimated tonnage range (over 10,000T per year). To propose a restriction on such a broad range of applications needs consideration for the feasible environmental emission of the individual processes, which is lacking in the proposal.  To conclude, the access to clear, wearable and durable eye glasses is a essential use for many, and its supply to consumer would be adversely affected with the restriction proposal as currently stands. |
| Answer to specific info request 1:  Medical Devices; Other niche applications Eyewear – coatings for ophthalmic lenses which are easy to clean, hydrophobic, oleophobic, scratch-resistant, anti-reflective and impart minimal eye fatigue; sportswear applications, such as swim goggles, visors; COTEC – fluoropolymers for hydrophobic coatings; oleophobic coatings; physical vapour deposition (PVD) coating Safety; PPE, prescription safety eyewear Plastic sheeting; Polycarbonate sheet, anti-fog film lining for commercial freezer door applications (placement?) Defence industry (dossier does not researched in detail); military-grade safety eyewear Automotive; anti-fog coating for headlamps and gauges 3D resin technology; AR-VR coatings; specialty coatings for electronics |
| Answer to specific info request 5:  The functionality and availability of many fluoropolymers used in the sectors and sub-uses aforementioned cannot be reasonably replaced by new chemistries. Fluoropolymers used in essential use goods/applications, such as medical articles, must be granted time-unlimited derogations to avoid widespread market disruption. The time-unlimited derogation should also include consideration for the manufacture supply to ensure raw materials necessary for derogated uses are still available in the EU market to avoid replacement with lower quality, non-EU sourced products, which would increase the risk potential for environmental emissions and comes with less tonnage visibility. Due to low concentrations/niche markets, very low tonnage contribution to overall tonnage estimates, and negligible emissions if product is used as intended. |

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| 9549 | Date:  2023/09/25 21:52  Content:  Scope or restriction option analysis  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  National NGO  Org. name:  Green Science Policy Institute  Org. country:  United States of America  Attachment:    <redacted>  Privacy statement:  We could not confirm with 100% certainty that these products were PFAS-free, therefore we did not want to share them publicly. | General Comments:  The Green Science Policy Institute has over ten years of experience studying PFAS and collaborating with PFAS scientists on exposure, health, and ecological harms due to the use of this chemical class. We would like to express our full support for the restriction of PFAS, including fluoropolymers and fluorinated gases. Please see the attachment in Section IV for our full comment. |

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| 9550 | Date:  2023/09/25 21:53  Type:  BehalfOfAnOrganisation  Org. type:  National Authority  Org. name:  <redacted>  Org. country:  Canada  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 6:  One PFAS use that does not yet seem to be identified is forensic science, more specifically, fingerprint detection. Forensic science is a small sector compared to those already identified in this PFAS restriction report, yet an important one in terms of law enforcement, crime resolution and reduction, and public safety. Fingerprint researchers and forensic practitioners need sufficient time to conduct research and to validate suitable solvent alternatives prior to a complete ban of PFASs. We are already under a time crunch with 3M’s announcement of their plans to cease manufacturing PFASs by end of 2025. Currently, 3M Novec HFE7100 and HFE71DE are the primary carrier solvents in all three amino acid sensitive chemical formulations that are used to develop fingerprints on porous exhibit items (e.g., paper, envelopes, cheques, magazines, cardboard) in criminal investigations in Canada and internationally. These solvents help to carry other reagents to the fingerprint residues that are absorbed into the porous surfaces. We are aware of one other solvent that is currently used in amino acid reagents for casework by two international police agencies. Unfortunately, these agencies have also reported explosions in their laboratory facilities when using this solvent. There are approximately 160 police agencies in Canada, covering federal, provincial, and municipal jurisdictions. We believe that the majority of these agencies are unaware that a potential PFAS ban is being considered (we were not aware that the Government of Canada was seeking input from stakeholders in 2021; we only found out about this opportunity from a European counterpart a few weeks before the submission deadline) and that HFE7100/DE will no longer be available within a couple of years. While 3M made their announcement in Dec 2022, we were not made aware until Mar 2023 by a forensic supply distributor, who has direct contact with the manufacturer. Several Canadian police agencies were unaware in May 2023 at an in-person event and one police agency reached out to us only a couple of weeks ago. Many Canadian police agencies are not in a position to conduct fingerprint research, as the forensic practitioners (primarily police officers) are occupied with attending and processing crime scenes, processing exhibits, etc. While our organization found out about a potential PFAS ban in Europe back in 2020, we could not start researching alternative solvents until summer 2023 due to staff shortages, the COVID-19 pandemic (limited access to laboratory, fingerprint donors), and other organization-driven priorities. We were the first Canadian police agency to conduct a research study investigating an alternative solvent to HFE7100/DE that appeared promising based on three recent peer-reviewed publications (research conducted in three different countries), only to find out in June 2023 that it would also be considered a PFAS, depending on which definition was used. That being said, the manufacturer stated it does not plan to stop production. Unfortunately, there were some operational issues that should not be ignored (e.g., laboratory renovations likely required to properly store compressed gas cylinder; more expensive glassware needed to safely store working solutions; access to refrigerator/freezer required; alternative solvent caused an increase in ink diffusion). Our organization hopes to assess other alternative solvents within the next year. Multiple research studies are required prior to recommendation for implementation into operations. While we may not be able to provide you with the exact information desired, we hope the following will provide you with some useful insights or aspects to consider: - When fingerprint researchers/forensic practitioners were looking for an alternative solvent to CFCs (Freon 113) which were being banned in the 1990s, it took about five years before HFE products were considered suitable. Additional years were required to optimize the chemical formulations for effective fingerprint development. - The amount of porous exhibit items to process for fingerprint evidence can various depending on where a forensic identification unit is located in Canada. For example, in a past national field trial, a unit only processed one porous exhibit in a year. During the same time period, another unit processed over 1760 porous exhibits belonging to a single criminal investigation, plus additional items from other investigations. Therefore, the amount of solvent required will vary depending on caseload. Please note, our organization alone has ~65 units across the country. - Our organization adheres to the International Fingerprint Research Group guidelines, which break down research studies into four main phases: proof-of-concept, optimization/comparison, pseudo-operational to casework trials. Therefore, several years are needed to compare HFE7100/DE to other solvents. Not all fingerprint researchers are able to collaborate with police agencies. - While the focus may be to find an alternative solvent for fingerprint development, it is important that additional research is conducted to determine the impact of/on other forensic analyses (e.g., DNA, questioned documents), as the goal is to maximize evidence recovery. Not all police agencies have easy access to these other disciplines to collaborate. - Many forensic organizations also need to meet accreditation standards (e.g., ISO 17025). Therefore, research conducted needs to be scientifically/statistically sound and robust. - While there may be alternative solvents to explore, we may run into issues with manufacturers we have never dealt with before. Also, forensic science is a niche application and therefore not likely to represent a large portion of solvent manufacturers’ client/product portfolio. Therefore, additional discussions may be required for alternate packing sizes, etc. |

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| 9551 | Date:  2023/09/25 22:01  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Other contributor  Org. name:  European Society for Medical Oncology  Org. country:  Switzerland  Attachment: | General Comments:  The European Society for Medical Oncology (ESMO) notes the draft proposal’s aims to prevent PFAS accumulation in the environment and food chain and welcomes its efforts to improve human health. However, it is pivotal that such action is based on a comprehensive and consistent review of the available evidence as there are growing concerns about the possible impact of the draft proposal on the production, availability and manufacturing of cancer medicines. |
| Answer to specific info request 1:  Pharmaceuticals, medical devices, excipients, tarting materials and chemical intermediates, reagents, solvents, catalysts, auxiliaries. |

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| 9552 | Date:  2023/09/25 22:08  Content:  Scope or restriction option analysis  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  CERN  Org. country:  Switzerland  Attachment: | General Comments:  The European Organization for Nuclear Research (CERN) https://home.cern/ is an intergovernmental Organization established in 1954. The Organization has its seat in Geneva, but its site straddles the Franco-Swiss border. CERN is funded by 23, mostly European, Member States, and its mission is to provide for collaboration in particle physics research of a pure scientific and fundamental character and in research essentially related thereto. At present, more than 10 000 scientific users from research institutes all over the world are using CERN’s installations for their experiments. To this end, it designs, builds and operates particle accelerators. CERNs flagship accelerator, the Large Hadron Collider (LHC) was approved in 1994 and went into operation in 2009. The LHC is part of a large complex of accelerators. Following a major upgrade to be completed around 2035 (High Luminosity LHC – HL-LHC), it is set to operate until the mid- 2040s. The LHC serves several experiments, among them four worldwide scientific collaborations that use giant detectors to study particle collisions produced by the accelerator. These detectors were designed and built at the same time than the LHC. CERNs scientific activities rely on the availability of efficient and reliable particle detection systems, i.e. particle detectors and associated cooling systems, that must operate in a particularly harsh environment of very low temperature and high ionizing radiation fields. These detection systems use F-gases (cf. section 6). Despite an extensive R&D program, focusing on the recirculation and recuperation of gases and more environmentally friendly particle detection solutions, no viable alternative can currently be implemented for this specific use.  CERNs operation further implies the use of various cooling systems using F-gases, such as hundreds of chiller units and heat pumps. For these units, CERN has already started to replace HFC by HFO to be in line with Kigali amendment. Given the number of installations concerned and the fact that their refurbishment can only take place during extended maintenance periods (2 years every 5-6 years), this transition will take at least 12 years. The cost of the refurbishment is currently estimated at least 50MCHF.  In the light of the above CERN requests the following to be considered for the future regulation: - CERN research activities require an exclusion of F-gas restrictions until the end of the current physics program linked to the operation of HL-LHC, provided alternative detector technologies for future research programs are available in due time. An additional derogation for research activities and, in particular particle detection and related cooling is required in this context. - A clarification of scope and harmonization of objectives would also be welcome with respect to the current initiative and F-Gas Regulation EU No 517/2014. This would avoid un-necessary ambiguities and uncertainties. |
| Answer to specific info request 1:  The use of the F-gases in the particle physics experiments as gases for particle detection and related cooling is not included among the uses contemplated in Table 9 of the restriction proposal neither in the list of proposed derogations. |
| Answer to specific info request 4:  An extension of the F-gases use for particle detection and related detector cooling is needed for the continuation of the particle physics research activities until the end of the current physics program of the HL-LHC, planned to end by the mid 2040s. Possibility to recycle the F- gases in use during- and at the end- of the use period should remain available. |
| Answer to specific info request 5:  Please see request number 6. |
| Answer to specific info request 6:  Please see attached document. |

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| 9553 | Date:  2023/09/25 22:14  Content:  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  National NGO  Org. name:  Safer States, on behalf of 19 NGOs  Org. country:  United States of America  Attachment: | General Comments:  Safer States is submitting the following comments in strong support of the proposed restriction of per- and polyfluoroalkyl substances (PFAS) on behalf of the following 19 organizations based in the United States (US): Alaska Community Action on Toxics, Alliance of Nurses for Healthy Environments, Center for Environmental Health, Clean and Healthy, Clean Cape Fear, Clean Water Action, Consumer Reports, Defend Our Health, Earthjustice, Ecology Center, Great Lakes Regional Center of the National Wildlife Federation, Merrimack Citizens for Clean Water, North Carolina Conservation Network, Oregon Environmental Council, Responsible Purchasing Network, Safer States, Vermont Conservation Voters, Vermont Natural Resources Council, Women's Voices for the Earth.  Safer States is a national alliance of US environmental health organizations and coalitions dedicated to building a healthier world by protecting communities and our planet from harmful chemicals and plastic pollution.  Please note that because the ECHA comment submission form was not conducive to footnotes, a fully referenced and footnoted version of our comments have been attached as reference  Introduction  PFAS pollution is now a global crisis. Toxic and persistent PFAS “forever” chemicals are present in the blood, breastmillk, organs, and tissues of humans worldwide. PFAS are widespread drinking water pollutants and are also contaminating rivers, lakes, air, soil, and wildlife. Concentrations of PFAS in rainwater now exceed proposed US drinking water standards, leading scientists to declare that the planetary boundaries for PFAS chemicals have been exceeded.  In the US, several states have been forced to issue advisories warning against eating local fish, turkey and deer because the concentrations of PFAS are too high to be consumed safely. So many farmers in the state of Maine have lost their livelihoods due to pervasive PFAS soil contamination that millions of government dollars have been set aside to help provide relief. More than 200 million Americans are estimated to be drinking PFAS contaminated drinking water, and the US federal government recently pledged $5 billion over five years to begin to address the widespread PFAS pollution problem. It is all too clear that the PFAS crisis is extremely expensive, both in terms of financial costs and the toll on human health and livelihoods.  The European Union has an opportunity to be a global leader in phasing out all uses of these substances that are toxic, mobile and persistent. Safer States and the undersigned organizations urge the European Union to adopt a comprehensive PFAS restriction with very limited derogations for only those uses where the use is critical for human health or safety the functioning of society and alternatives are currently unavailable.  Comments and information pertaining to the proposed scope and restriction options:  ● The entire class of PFAS should be phased out, using persistence as the underlying basis for the restriction.  Chemical regulation has a long history of regrettable substitution. If one harmful chemical is restricted, industry selects a similar chemical from the same class to be used in its place – with regulators only recognizing when it is too late that this substitute compound is also problematic. This cycle has already been demonstrated with PFAS: When highly toxic and persistent PFOA and PFOS were phased out as processing aids in fluoropolymer production, new toxic and persistent chemicals known as Gen-X were used in their place. When the industry could no longer deny that long-chain PFAS were harmful, they moved to short-chain PFAS and falsely claimed that they were safe. Decades of industry regrettable substitution combined with a regulatory approach focused on restricting one chemical at a time has led to global PFAS contamination.  The proposal to regulate the entire class of PFAS chemicals is the scientifically grounded path forward that will avoid the cycle of regrettable substitution and focusing on the fundamental characteristic of the chemicals’ persistence is the correct approach. As a recent scientific paper noted: “if a chemical is highly persistent, its continuous release will lead to continuously increasing contamination” that will take “decades, centuries or even longer to reverse” and lead to “increasing probabilities of the occurrence of known and unknown effects.”  Both the scientific and the business communities are embracing the class based approach to PFAS. The Global PFAS Science Panel, for example, has been outspoken on the need to ban all uses of all PFAS chemicals. Many global companies including Lacoste, Fjålraven, Levi Strauss, Starbucks, and McDonalds have taken action to phase out the entire class of PFAS from their products. Recently, almost all of the major global third party textile certifiers including OEKO-TEX, Bluesign, ZDHC and GOTS have updated their standards to phase out the use of the entire class of PFAS chemicals.  ● There should be no exemptions for PFAS subgroups allowed under the restriction, including fluoropolymers and F-gases.  It is critical that no subgroups of PFAS, such as fluoropolymers or F-gases, are exempted from the proposed restriction. Such exemptions would undermine the effectiveness of the PFAS phase out and would lead to continued impacts on human and environmental health for decades or generations to come.  The chemical industry has claimed that fluoropolymers and F-gases are important to enable the “clean energy” transition, yet no energy technology can be considered “clean” if it relies on highly toxic persistent chemicals that contaminate the planet. Alternatives already exist for many use cases for fluoropolymers and F-gases, and adequate transition times can be provided where there are not currently available alternatives. As an example of how innovation can drive the development of safer product designs, a University of Michigan review of the use of PFAS in solar panels found that “PFAS is not customarily used in solar panels because safer, effective alternatives have already been developed and commercialized.”  Similarly, the industry has lobbied for the exemption of F-gases such as HFOs and HFCs in PFAS regulations. Yet these chemicals can transform into ultra-short-chain PFAS known as trifluoroacetic acid (TFA), which are toxic to both humans and aquatic life, and a highly problematic drinking water contaminant. HFCs are also highly potent greenhouse gasses that are now listed for international phaseout under the 2016 amendments to the Montreal Protocol. Furthermore, a key feedstock to make some HFOs is carbon tetrachloride, a major, greenhouse gas and ozone depleting chemical which is also a carcinogen. For all of these reasons, we strongly advise you not to exempt F-gases.  There are many clear science and policy based reasons why fluoropolymer PFAS compounds must be included in the restriction proposal and phased out.  First it is important to note that restrictions on fluoropolymers already exist in the US: fourteen US, states including huge economies such as California and New York that have banned PFAS in one or more product categories do not exempt fluoropolymers. This includes bans on PFAS in apparel, rugs, cleaning products, cookware, dental floss, fabric treatments, firefighting foam, food packaging, hydraulic fracturing fluid, juvenile products, menstrual products, personal care products, pesticides, ski wax, and textiles. This is also the case in the 2 states that have effectively banned PFAS in all products: Maine and Minnesota.  Second, fluoropolymer production and use creates toxic PFAS pollution. PFAS polymers are made using other harmful PFAS chemicals, which are subsequently released into the environment when waste byproducts enter air and waterways. In fact, when scientists studied the fate of a commonly used group of toxic PFAS, they estimated 80% of those chemicals made since the 1950’s have been released to the environment from PFAS polymer “manufacture and use.” Certain fluoropolymers release toxic PFAS chemicals during their use, posing acute and chronic risk to human and ecological health. Workers in plants making or using fluoropolymers also may be exposed to serious hazards.  Third, fluoropolymers can cause illness and injury. Respiratory illnesses associated with normal consumer uses of fluoropolymer-containing products such as waterproofing agents and sealants remains an ongoing problem that has “occurred for many years in many different countries.” The Centers for Disease Control and Prevention have reported cases of “severe acute respiratory illness” linked to the use of a fluoropolymer-based shoe spray which was later recalled by the manufacturer. The Plastics Industry Association has noted in their own materials that fluoropolymer exposure can cause the flu-like condition known as “polymer fume fever.” It has also been known for decades that fumes from Teflon® pans can kill birds. Clearly exposures during fluoropolymer production and use have caused illness and injury, making a clear case that these are harmful materials.  Fourth, fluoropolymer production emits "climate super-pollutants” such as HCFC-22 and HFC-23, which are 5,280 and 10,800 times respectively more potent at warming the atmosphere than carbon dioxide, on a twenty year timescale. The emissions of these two compounds from just a single PFAS polymer manufacturing plant are the equivalent of the annual carbon dioxide pollution from 750,000 passenger cars. HCFC-22 also destroys the health-protective stratospheric ozone layer.  Fifth, disposal of PFAS polymers poses serious threats. Landfilling of fluoropolymers can lead to contamination of nearby soil and groundwater and can contribute to releases of microplastics and, in some cases, other PFAS chemicals. Deep well injection of manufacturing waste relocates the threat and creates the possibility of spills and leaching into drinking water. Incineration of fluoropolymers creates toxic emissions that can harm frontline communities and spread far beyond their source. Most municipal incinerators are not designed to handle highly corrosive materials formed when fluoropolymers break down. These same serious disposal issues are also present for the PFAS chemicals used to make the polymers.  Fifth, the PFAS crisis began with polymers – let’s not repeat history PFAS pollution first came to light from DuPont’s manufacture of the fluoropolymer Teflon® which led to massive contamination still causing harm today. We should learn from this disastrous history and take action to protect public health and the environment from these persistent toxic chemicals.  ● The PFAS restriction should continue to rely on the OECD’s PFAS definition, and not narrow the set of PFAS covered by the proposal.  As US-based organizations, we strongly urge the EU to continue to rely on the OECD PFAS definition in restriction regulations and dismiss any requests to move to a significantly narrower and weaker definition. How the class of PFAS compounds is defined has serious implications for regulation, litigation, monitoring, research, and impacted communities. If policies rely on narrow definitions of the PFAS class, fewer of these toxic compounds will be restricted or cleaned up, resulting in continued harm to people and the environment.  Notably, almost all of the US states that have laws or policies restricting PFAS uses rely on a slightly broader definition that is very similar to the OECD definition, defining PFAS as organic chemicals containing ‘‘at least one fully fluorinated carbon atom.” At least 18 states including Arkansas, Arizona, California, Colorado, Connecticut, Kentucky, Hawaii, Illinois, Louisiana, Maryland, Maine, Minnesota, New Hampshire, Nevada, New York, Rhode Island, Vermont, and Washington define PFAS in this fashion, with no carve outs for any subclasses of PFAS. An EU PFAS restriction that relies on the OECD would therefore provide consistency in the global marketplace.  The US Environmental Protection Agency (EPA), in contrast, has used several different definitions for PFAS at different times and in different circumstances. Under one flawed PFAS definition, the agency excluded polyvinylidene fluoride (PVDF), the second most highly produced fluoropolymer (after PTFE), at least two PFAS chemicals found in the blood of residents living near a PFAS manufacturing plant, as well as other high production volume PFAS. This “working definition” was widely criticized by scientists, impacted communities, advocates and former federal agency officials.  Most recently, in August 2023, the US EPA has announced that it would not have any single formal definition for PFAS, but would instead take a “case-by-case” approach for what the agency considers a PFAS. Former EPA scientist and head of the US National Toxicology Program Dr. Linda Birnbaum had this response: “This is not a new definition – it is a lack of definition, and it makes no sense… It is just going to lead to terrible confusion.” In short, the United States federal government is inconsistent and unclear when it comes to the question of what set of chemicals should be considered to be PFAS and the EU should consider its comments on this matter with that perspective.  Comments and information pertaining to the socio economic analysis:  ● The costs of PFAS monitoring and clean up are staggering, as demonstrated by money already spent by US local, state and federal governments. Safer States has compiled a database detailing many of the direct government costs associated with PFAS contamination to date. The data was collected through a non-comprehensive review of state government budgets, federal government reports and media articles and should be considered a significant underestimate of the true costs of PFAS contamination. The figures include both actual and estimated costs provided by local, state and federal governments, and are generally one-time costs (rarely including ongoing and maintenance costs).  We have provided a summary of the data below in the hopes that it can assist EU regulators with the socio economic analysis of the proposed PFAS restriction. Further details about the data can be provided upon request. Given that the proposed EU PFAS restriction does not address firefighting foam, costs clearly associated with this contamination source have been excluded where possible. With the data sources we relied on, it is difficult to provide incremental costs (i.e. those related to implementing the proposed restriction as compared with not implementing it), but the data do provide a demonstration of the staggering financial liability the EU is facing if PFAS chemicals continue to be used.  US State Government PFAS expenditures by cost category (in US$)  - Drinking water treatment / new water supply: $ 617,487,853 - PFAS testing / monitoring: $ 56,311,000 - Cleanup of PFAS contaminated landfills: $ 24,584,228 - General PFAS cleanup: $ 538,112,363  US State Government PFAS expenditures by contamination source category (in US$)  - PFAS chemical manufacturing: $ 94,600,000 - Product manufacturing: $ 1,450,000 - Landfill contamination: $ 24,584,228 - Unclear / multiple contamination sources: $ 1,115,861,216  It should also be noted that in addition to the costs detailed above, the US federal government has allocated $5 billion USD over five years to begin to address contamination from PFAS and other emerging contaminants.  Given the exponentially escalating costs to communities to manage the pollution, to date 27 State Attorney’s general have initiated action to secure resources from chemical manufacturers and key users to help pay for clean water. These costs are likely just the tip of the iceberg, especially since healthcare costs associated with PFAS impacts are difficult to quantify yet known to be sizeable.  Comments and information pertaining to the transitional period:  ● Transitional periods should be as short as possible, and no time unlimited derogations should be allowed. While there may be use cases where no viable PFAS alternative currently exist, strong government action is a key lever for spurring innovation. The EU should be aggressive in setting short phase out deadlines for PFAS uses and trust in the power of human ingenuity when given a clear task and the right incentives. It is also critical that the two proposed time unlimited derogations for plant protection products and biocidal products be amended to include a clear phase out deadline. Such time unlimited derogations will not provide industry the needed incentive to identify safer alternatives for these PFAS uses and these toxic and persistent chemicals will continue to be used for an indefinite period of time, causing untold human and environmental harm.   ● Transitional periods should not extend longer than the phase out deadlines present in US state laws. As noted earlier in these comments, fourteen US states have already passed laws or enacted policies that ban the entire class of PFAS chemicals in a wide variety of product categories. As the EU considers what kind of transitional periods are needed for different PFAS uses, they need not extend beyond the phase out deadlines already adopted in one or more US states. A detailed spreadsheet of state PFAS bans has been submitted with these comments as an attachment and is also summarized below.  While different US states laws incorporate different timelines, the earliest phase out dates for these product categories are as follows: ● Apparel: December 2025 ● Carpets and rugs: January 2023 ● Cleaning products January 2025 ● Cookware: January 2025 ● Dental floss: January 2025 ● Fabric treatments: January 2023 ● Food packaging: January 2022 ● Hydraulic fracturing fluid: January 2024 ● Juvenile products: January 2023 ● Menstrual products: January 2025 ● Personal care products: January 2025 ● Pesticides: January 2030 ● Ski wax: January 2023 ● Textiles: July 2023 for indoor textile furnishings and upholstery; January 2025 for other textile products  In addition, it is important to note that two US states have also passed laws that ban PFAS in all products, other than where PFAS use is currently unavoidable. The phase out deadlines for all PFAS uses in these states are: Maine (January 2030) and Minnesota (January 2032).  Conclusion: The class of PFAS chemicals is collectively so persistent and toxic that they require urgent and comprehensive action to prevent further human health and environmental harm that will last for generations to come. We urge the EU to phase out the entire class of PFAS using persistence as the underlying basis for the restriction. There should be no exemptions for PFAS subgroups allowed under the restriction, including fluoropolymers and F-gases. The PFAS restriction should continue to rely on the OECD’s PFAS definition, and not narrow the set of PFAS covered by the proposal. Transitional periods should be as short as possible, and no time unlimited derogations should be allowed. Strong government action is a key lever for spurring innovation and this is what is needed to end all uses of toxic PFAS chemicals. |

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| 9554 | Date:  2023/09/25 22:13  Content:  Hazard or exposure  Environmental emissions  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Regional or local authority  Org. name:  Kemikaliecentrum, Miljöförvaltningen, Stockholm Stad  Org. country:  Sweden  Attachment: | General Comments:  The City of Stockholm has established a resource center with specialized expertise in chemistry. The Chemical Center is, among other things, a support function for the City with the vision of achieving a toxin-free Stockholm.  The Chemical Center at the City of Stockholm would like to contribute to the consultation on the proposed restriction of per- and polyfluoroalkyl substances (PFAS). We support Restriction Option 1 (RO1) and firmly believe that a total ban on PFAS would greatly benefit the well-being of our citizens, the environment, and our municipal operations.  The Chemical Center conducts health-related environmental monitoring in indoor environments. As a part of this monitoring, PFAS levels in dust were assessed at 20 preschools, revealing considerable levels of PFAS in all 20 dust samples (see attached analysis results), in which some were exceeding the new proposed PFAS limits (i: 25 ppb, ii: 250 ppb). For example, in one dust sample, concentrations of a single PFAS substance (6:2 diPAP) reached 42,000 ppb. These findings indicate the presence of PFAS sources in these indoor environments, which may have direct or indirect implications for the well-being of children as well as staff. This is a matter of concern, as the City’s objective is to offer our citizens a good and safe indoor environment.  Furthermore, we have encountered challenges in determining whether our suppliers' products contain PFAS or not, as suppliers typically only analyse a few individual PFAS substances and may lack knowledge of the presence of PFAS in their products. This lack of information and transparency hinders our ability to verify compliance with our procurement requirements and prevent unintentional contributions to PFAS usage.  As a municipality, the City of Stockholm envisions no obstacles to completely phasing out PFAS from the municipality’s contracts and assortments, with some exceptions. These include, for example, electronic equipment such as computers, since PFAS might exist in the circuit boards. Although there are alternatives to PFAS in many sectors, further research and development is needed to identify and promote safer options where PFAS substitution remains challenging. A ban on PFAS would encourage innovation in this field and expedite the transition to safer alternatives. Additionally, a total ban on PFAS might encourage manufacturers and consumers to reassess the necessity of all functions provided by PFAS additives in products and materials.  A total ban on PFAS could also incentivize the development of standardized and commercially available analytical methods for measuring total PFAS content. This would simplify compliance verification of procurement requirements and enable more accurate monitoring of PFAS levels. Furthermore, it would facilitate informed decision-making regarding the products and materials procured, used, and produced. This, in turn, could lead to a more deliberate and proactive approach to eliminating PFAS and potentially drive innovation towards more sustainable alternatives that do not rely on harmful chemicals.  In sum, a total ban on PFAS would optimize the City’s efforts to prevent unintentional contributions to PFAS usage, encourage innovation, and expedite the transition to safer products and materials, ultimately creating a better and safer environment for our citizens. |

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| 9555 | Date:  2023/09/25 22:19  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Documents are confidential to protect our commercial interests and includes technical evaluations that contains intellectual property and R&D studies | General Comments:  Our pumps are used to dose automatically and safely pure chemicals into water under pressure without human contact of these chemicals that are used and necessary for our customer’s process to avoid overdosing and hand manipulation. Our products are eco designed and iso 140001 certified as such. |
| Answer to specific info request 1:  Our pumps are used in Industrial food process and water treatment application which fall under Annex XV. As pump manufacturer we have other mission critical flow application to dose pure chemicals. See section 6. |
| Answer to specific info request 5:  Fluropolymers > 12 T per year Fluoroelastomers > 2 T per year Data available as confidential |
| Answer to specific info request 6:  As a pump manufacturer, we consider that the sector of pump manufacturer is considered in a very limited way in annex XV report as the use of PFAS for pumps generally apply on Sealing (FKM, TFE/P, FFKM) or Housing /Structural mechanical parts (PVDF) in contact with chemicals. Evaluation of alternatives, costs and R&D status are described in confidential documents . |
| Answer to specific info request 8:  Pumps we manufacture and that are generally part of Mechanical engineering equipment (eg. Industrial machinery, non-road mobile machinery, pumps, valves, compressors, pressure gas equipment, etc.) are not considered, or in very limited way, in this annex XV report and rely on the use of PFAS for several applications as described in section information on alternatives |

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| 9556 | Date:  2023/09/25 22:21  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  See enclosed the approval of one of our PTFE compound materials with USP Class VI approval with direct blood contact approval. This is proof that we are allowed to use the material for the highest requirements in the medical sector. These approvals are also available for FDA, BAM and KTW, which can also be submitted on request. | General Comments:  There is no alternative to the use of PTFE and its compounds in industry. We advocate the exclusion of the 38 fluoropolymer substances from the PFAS regulation, as they differ significantly from the other short-chain PFAS substances. We hold the highest possible approvals for our PTFE components in automobiles, medicine and the water sector, which prove that they are safe to use. The KTW approval certifies, for example, that no substances are released from the seals we produce that influence the quality of German drinking water. This is also the case for the English WRAS and the American NSF approval. The FDA approval for our materials also certifies that they are safe materials that are used in mechanical engineering in direct contact with food. We ourselves hold USP Class VI approval, which enables us to supply components for dialysis machines. This application in particular has no possible alternatives. Due to complicated cleaning cycles during operation, it must be resistant to complex cleaning chemicals. In addition, this bellows has complex mechanical and geometric requirements and must, for example, work in very high temperature ranges, where a possible alternative such as PE-UHMW already reaches its limits. The geometry is very delicate and flexible, which is why e.g. PEEK material is not an alternative. Although this makes it possible to cover the temperature range, it greatly exceeds the cost framework as well as the ability to produce the delicate structures in question.  Another example, in addition to the application described in the medical sector, is the application of our materials in the automotive sector. In addition to applications in the ESP area, we are also represented here as a sealing ring directly in the brake system. Here, too, there is no possible replacement material that can guarantee both the high temperature requirements and the resistance to the various hydraulic oils.  With around 180 employees and an approximate processing capacity of around 250 tonnes of PTFE per year, we supply 100% of the material affected by the restriction. This dossier is therefore a threat to the existence of our company. This represents an annual turnover of around 15 million euros for our company. This multiplies many times over along the supply chains. As a supplier of mainly sealing technology, we frequently deliver C-parts. C parts with an A function. This means that very complex assemblies at 2nd and 1st tier cannot be produced without our components. |
| Answer to specific info request 1:  We mainly deliver to the automotive sectors; Medicine (direct blood contact of our components), components in the sanitary sector, electrical industry, general mechanical engineering, food sector, chemical pump sector. |
| Answer to specific info request 2:  We assume that when PTFE is fed into the industrial recycling process, no PFAS substances are produced during incineration. For this, it is important to create a closed recycling chain. The automotive industry is already pursuing this approach with the End-of-Life Vehicles Directive. |
| Answer to specific info request 4:  The company Dyneon in Gendorf has a test facility for the chemical recycling of PTFE material. This procedure should definitely be pursued even after the closure of the 3M locations in Germany. |
| Answer to specific info request 5:  We expressly oppose exemptions for PTFE materials and plead for the removal of the material from the restriction proposal. |
| Answer to specific info request 6:  see our two examples in our general statment. Dialyse in the medicine sector and sealing rings in the automotive brake system. A substitution of PTFE materials in industrial applications is not possible for three reasons: The temperature resistance up to 250 °C excludes almost all possible plastics or goes into areas such as Vespel, which are not economical as prices would multiply here. Furthermore, an outstanding feature of PTFE is its almost universal chemical resistance to a large number of chemicals used in industry. Thirdly, the material's outstanding sliding properties are worth mentioning, which makes it ideal for use in sealing applications, for example. The economic damage would be a total catastrophe for us, as we are 100% specialized in processing high-performance fluoropolymers. |

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| 9557 | Date:  2023/09/25 22:24  Content:  Scope or restriction option analysis  Baseline  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  DLB Gummiformteile GmbH  Org. country:  Germany | General Comments:  As a manufacturer of rubber covered rollers, we primarily supply companies in the packaging industry. The covers we produce are directly required for the production of food packaging materials and cannot be substituted because of their specific heat resistance and dehesive properties. When used as intended, no hazards are to be assumed. FEP and PFA and ETFE are known as "polymers of low concern"( PLC) as defined by the OECD. They are not high risk materials as they are not water soluble, not bioavailable or bioaccumulative, inert, stable and non-toxic and do not contain harmful PFAS materials. As a manufacturer of Technical Rubber Goods we produce different metal parts coated with FKM because of the heat resistance, elasticity and strength at high temperatures which no other elastomer shows. These parts are used in the sectors Electronics and semiconductors, Transport, Construction. |
| Answer to specific info request 6:  a: No data b: thermal resistance, physical stability and elasticity at high temperature, dehesiveness c: 10 d: No alternatives because of the required combination of chemical inertness, dehesive behaviour, chemical resistance, physical stability, endurance e: no information f: no information g: no information as our customers do not inform us about their business. In case of restrictions of elastomeric PFAs they surely will be substituted by other elastomers with dramatically raising costs because of their worse behaviour. This will be favorable for the elastomer industry, not for their customers. |

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| 9558 | Date:  2023/09/25 22:25  Content:  Description of analytical methods  Type:  Individual  Country:  Netherlands  Attachment:  <redacted>  Privacy statement:  The reason for keeping this confidential is the protection of intellectual property. This is needed, as the confidential information was submitted to a peer reviewed scientific journal, and is subject to acceptance by that journal for publication. | General Comments:  Chemicals are part of almost every aspect of our lives, from the consumer products and the food we consume, to the buildings we live in. Some of these chemicals may interfere with the health of humans and ecosystems and contribute to other undesirable effects such as climate change. Societies have therefore instituted measures to control and minimize the risks of chemicals at the national and international levels. Such risk governance typically includes risk assessment based on hazard and exposure, setting limits on the production and use of the most harmful chemicals and emissions to the environment, enforcement of regulations and monitoring the effectiveness of the measures taken. These steps depend on access to pure chemical reference standards, also referred to as ‘authentic standards’, ‘native standards’, or just ‘standards.’ However, except for the most highly regulated areas, such as pesticides and pharmaceuticals, such standards are often not readily commercially available, hampering the ability of scientists to produce the data currently required for risk governance. This raises a critical question: is the current approach to governing chemicals, and the lack of chemical reference standards, able to protect humans and nature from harm, and if not, what measures could be taken to improve the situation?  We outline the dependence of current risk governance on access by scientists to chemical reference standards (aka 'authentic standards'). We illustrate these issues using per- and polyfluorinated alkyl substances (PFAS), where standards are only commercially available for a small percentage of the class. The very limited availability of reference standards undermines the production of independent scientific evidence needed to support chemical risk governance and to protect society and the environment.  Possible ways to improve the situation include (i) guaranteeing access to chemical reference standards by creating a reference standards repository, (ii) redefining the level of confidence sufficent for regulation and providing alternative options for chemical identification and quantification when reference standards are not available, and (iii) reconsidering other options for the governance of chemical risk when reference standards are lacking, such as regulating the class of PFAS. |
| Answer to specific info request 10:  We outline the dependence of current risk governance on access by scientists to chemical reference standards (aka 'authentic standards'). We illustrate these issues using per- and polyfluorinated alkyl substances (PFAS), where standards are only commercially available for a small percentage of the class. The very limited availability of reference standards undermines the production of independent scientific evidence needed to support chemical risk governance and to protect society and the environment. Possible ways to improve the situation include (i) guaranteeing access to chemical reference standards by creating a reference standards repository, (ii) redefining the level of confidence sufficent for regulation and providing alternative options for chemical identification and quantification when reference standards are not available, and (iii) reconsidering other options for the governance of chemical risk when reference standards are lacking, such as regulating the class of PFAS. |

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| 9559 | Date:  2023/09/25 22:26  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Norway  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Transport: combustion engine system |

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| 9560 | Date:  2023/09/25 22:28  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Other contributor  Org. name:  European Society of Endocrinology  Org. country:  United Kingdom | General Comments:  ESE welcomes the PFAS restriction proposal and firmly stands behind the motivations for this important public health measure that will benefit current and future generations as well as our general environment.  Strict regulation of PFAS and other Endocrine Disrupting Chemicals (EDCs) is pivotal to address the many adverse health outcomes linked with such exposures including altered reproductive function in men and women, abnormalities in reproductive organs, early puberty, immune system disruption, cancers, neuroendocrine tumours, respiratory problems, diabetes, obesity, cardiovascular conditions, altered nervous system development and function, and learning disabilities. These associations have been described extensively in peer reviewed literature.  PFAS differ from other EDCs by their highly persistent and bioaccumulative nature, which leads to contemporary exposures having effects on human and animal health as well as our environment far into the future for generations to come.  While for many PFAS no or only limited toxicological information exists, those that have been substantially studied are connected to concerning health outcomes in both humans and animals. For example, PFOS and PFOA have been associated with lower birth weight, adverse effects on the liver, disrupted serum lipids, and immunotoxicity. Especially concerning is the link between exposure and reduced response to vaccinations at a time when countries in Europe and across the globe continue to struggle with COVID-19 and other viruses.  Another area where PFAS distinguishes themselves from other EDCs is their ubiquitous presence in the most vulnerable of our society, namely “the unborn”. Studies of pregnant women have shown that PFOS, PFOA and PFNA contamination not only occurs in the placenta and cord blood but also in vital fetal organs, most frequently in the liver and lung. Such exposure poses a risk for the unborn child’s health and development through life. Finally, there have been several studies linking PFAS to the thyroid function, which is essential for normal brain development and neurocognitive function.  Early life is a sensitive window of development when even small changes to the endocrine system can have long-lasting adverse effects on development and postnatal health. Such exposures should be eliminated immediately to ensure uncompromised development and health of all members of the society. |

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| 9561 | Date:  2023/09/25 22:32  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Regional or local authority  Org. name:  Provincie Gelderland  Org. country:  Netherlands | General Comments:  The province of Gelderland calls for a rapid and total ban of PFAS  This contribution reflects the position of the province of Gelderland on this consultation. The province of Gelderland supports the proposal for a complete ban on PFAS, to protect the environment and the health of our inhabitants. To avoid substitution of one PFAS for another, we support the fact that the restriction proposal targets the entire group of PFAS. Moreover, the province of Gelderland believes that it is irresponsible to postpone a ban. Since PFAS are forever chemicals and won’t disappear from our environment, it is undesirable to take 12 years to phase out PFAS. Especially given that the quality of soil, air and water are increasingly under pressure. In Europe, there is increasing attention to a healthy living environment and stricter standards are being set for pollution of soil, air and water through the Soil Health Directive, the Air Quality Directive and the Water Framework Directive. Setting strict environmental standards for PFAS while at the same time letting new PFAS into the environment is counterproductive.  A cross border issue Given the impact PFAS are already having on our living environment in combination with the uncertainties that still surround PFAS, the province also sees the importance of a European approach. The PFAS problem is transnational as is clear from the elevated PFAS concentrations in the river Westerschelde, which originate from a factory across the border in Belgium. Since 2020, the Netherlands has been working with Germany, Denmark, Sweden and Norway on a proposal for a European ban on PFAS (Per- and polyfluoroalkyl substances). On February 7th 2023, your agency published a proposal for a ban (restriction) on PFAS. In parallel, a consultation was issued to gather input on this proposal.  Why does the province of Gelderland support the restriction? One of the tasks of the province, as a regional authority, is to ensure a clean and healthy environment for its residents. PFAS are increasingly known to have harmful effects on the health of humans and animals. PFAS are generally very stable, once in the environment PFAS compounds spread easily through soil, air and water. PFAS are used in countless products, which means that PFAS are present in the environment throughout the Netherlands (for illustration, see references 1, 2 and 3). Research shows that all kinds of (consumer) products and waste streams contain PFAS and that people are exposed to PFAS even in their own homes (4). As a result of this ubiquitous presence humans, animals and the environment are permanently exposed to PFAS with potential risks to human and animal health. Research by the RIVM, the Dutch national institute for health and environment, shows that people in the Netherlands already ingest too much PFAS through food alone (5). People living in close proximity to Chemours (a fluorpolymer plant in Dordrecht) are even advised against eating from their own gardens (6) and at several locations in the Netherlands people are advised against eating self-caught fish (e.g. 7). The drinking water companies in the Netherlands (see the reaction submitted to ECHA by VEWIN) point to the inability to completely remove these substances during the production of drinking water. Lastly, in a few recreational lakes around Dordrecht the province had to give a negative swimming advice due to excessive concentrations of PFAS (8).  The province of Gelderland is one of the twelve provinces in The Netherlands. We have 2 million inhabitants and a surface of about 5.000 km2. Currently we are carrying out a costly remediation project on a former industrial site. At this site the soil contamination was created in a couple of years. PFAS has been found already deep in the groundwater layer. Groundwater is our major drinking water source. We are concerned there are more of these sites in our province. Presently we are working on an inventory of PFAS-contaminated sites. Apart from these point sources there is a ‘background’ contamination level of PFAS which has major impact on the possibilities for transport and application of soil in housing construction and agricultural projects.  Social importance Public concern about PFAS is high. This is mainly because the effects of PFAS on humans, animals and the environment are not yet clear. Residents living near a PFAS plant or near PFAS-contaminated land or water are rightly concerned about the effects on their health. Heightened media attention is increasing the public awareness of possible harmful effects and public support for these substances is decreasing.  The role of industry To date, several industries are continuing to produce and use PFAS, thus releasing them into the environment. Moreover, PFAS are released not only during the production process, but also during use and at the end of their lifetime. In most waste incinerators PFAS are not completely destroyed, which means that even after phase-out, PFAS will continue to be released into the environment. The province of Gelderland is aware that a total ban will demand a lot from the industry, but trusts in the inventiveness of the market to come up with sustainable, safe and circular alternatives. We believe that a rapid and total ban is a good incentive for companies to change their processes. Where exceptions are allowed, the risk assessment of PFAS should be handled more thoroughly. The province of Gelderland advocates a stricter burden of proof if companies want to continue using PFAS, as an exemption to the new regulation. A rapid total ban is therefore the only correct course.  References: 1. PFAS concentraties in de Zeeuwse Wateren, Universiteit Utrecht (2022) 2. Landsdekkend beeld van PFAS in Nederlands grondwater, RIVM (2021) 3. PFAS in seaspray, Vrije Universiteit Amsterdam (2022) 4. PFAS in products and waste streams in the Netherlands, Arcadis, 28 mei 2021 5. Risk assessment of exposure to PFAS through food and drinking water in the Netherlands, RIVM, 2023-0011 6. Risicobeoordeling van PFAS in moestuingewassen uit moestuinen in de gemeenten Dordrecht, Papendrecht, Sliedrecht en Molenlanden, RIVM, 2022-0010 7. Consumptie van producten verontreinigd met PFAS uit de Westerschelde, RIVM, 2002-0020 8. Risicoschatting van PFAS in recreatieplas Merwelanden in Dordrecht, RIVM, KU-2023-0013 |

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| 9562 | Date:  2023/09/25 22:35  Content:  Scope or restriction option analysis  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Austria  Company name confidential:  Yes | General Comments:  The uniform, indiscriminate approach as specified in the current PFAS-restriction should be reconsidered PFAS are a highly diverse substance group comprising up to 10,000 substances, whereas several subgroups already have been restricted under various regulations (e.g.: Montreal Protocol, Stockholm Convention, Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, REACH-Regulation). Introducing a separate restriction with different mechanisms increases administrative time and effort, especially along a global supply chain outside of the EU. We ask to apply the proven and globally acknowledged REACH-SVHC approach for all PFAS restrictions. The threshold for PFAS in the articles should be reconsidered. The proposed threshold of 25 ppb for PFAS in articles is not feasible and does not commensurate with the risk on article level. Our products are components within products that will be assembled further, therefore the risk of being exposed is minimal and concentrated on the manufacturing site, not in the use phase of the product. For a risk-based approach health & safety regulations, as well as waste regulations are much more appropriate to address the issue. Furthermore, ppb-level restrictions are impossible for PCB-Manufacturers to control and assess, since the global supply chain does not work in these dimensions since this includes impurities, or cross contamination from process chemicals (e.g.: cleaning). A threshold as established within the RoHS and REACH legislation of 1000 ppm is realistic to be monitored across global supply chain. The transitional period should be prolonged. The current transitional period is not sufficient to identify, implement and qualify alternative products along the supply chain. As PFAS are generally more expensive than non-PFAS materials in our supply chain, there is already an economic incentive to only use PFAS-materials where there is no alternative. Consequently, replacement and/or alternative material are not readily available. Additionally, our global customers rely on homogenous products from us and our suppliers, therefore individual changes from an individual supplier are not tolerated easily if their standard alternative suppliers can fill this gap. For standard improvements, where materials are already available on the market, we need approximately 5 years starting with R&D through testing to customer qualification. Therefore, if the restriction stands for our products as is, we request the full derogation of 12 years in order to remain competitive on the global market. Jeopardizing European Chips Act and Green Deal Goals The general PFAS-restriction in its current form would lead to a significant disadvantage towards the European Chip Act and its goal of establishing more production capacity within the EU boundaries. In the current competitive environment it would make production in the electronics sector impossible by disrupting global supply chains and thus not only discouraging current and new investment in production capacity, but also threatening the competitiveness of the existing facilities. Additionally, the transition towards a carbon neutral economy will become significantly more demanding, as the core features such as transition of the energy infrastructure system (smart grid), carbon neutral transport systems or smart home applications all require a considerable supply of electronic components. Minimal Impact According to the restriction dossier and the German UBA, the electronics/semiconductors and energy sectors currently contribute less than 2% of total PFAS emissions in the EU. UBA, Webinar: Consultation on restriction proposal for per- and polyfluoroalkyl substances (PFAS), ECHA, 5 April 2023, https://echa.europa.eu/-/restriction-of-per-and-polyfluoroalkyl-substances-pfass-under-reach Questionnaire 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. Contained in our PCB or IC-substrates. We source materials and components globally, and in turn our products are further enhanced by adding components at downstream production sites until they are finally assembled to end-products for consumers, the automotive or medical industry or other industrial use. Consequently, we don't have any control where our products eventually will be installed, therefore any use-based restriction will affect our entire production. In the end any restriction aimed at specific (end-)uses will affect the entire supply chain, and discriminate all similar PCB/IC-Substrate production since the production at our tier 3/4 production sites does not differentiate towards a specific end-use. Therefore, we highly recommend an integrated approach along the entire PCB and semiconductor industry. |
| Answer to specific info request 1:  Our input mainly covers “Electronics and semiconductor (Annex E.2.11.). However we source materials and components globally, and in turn our products are further enhanced by adding components at downstream production sites until they are finally assembled to end-products for consumers, the automotive or medical industry or other industrial use. Consequently, we don't have any control where our products eventually will be installed, therefore any use-based restriction will affect our entire production. In the end any restriction aimed at specific (end-)uses will affect the entire supply chain, and discriminate all similar PCB/IC-Substrate production since the production at our production sites does not differentiate towards a specific end-use applications. Therefore, we highly recommend an integrated approach along the entire PCB and semiconductor industry. |
| Answer to specific info request 2:  The PFAS present in our PCBs have a very low vapour pressure and therefore do not volatilise at room temperature in order to provide the required function during the product life time, and to perform well under more severe conditions than the rated operating conditions. Electronic products are collected and separated from the waste stream, thus ensuring a controlled recycling process and regulated under WEEE Directive 2012/19/EU Annex VII to WEEE Directive 2012/19/EU which sets the separate treatment criteria for the specified materials and components according to the Article 8(2). Other waste directives are based on finished products such as the Battery Directive and the ELV Directive. These directives ensure a well-monitored and controlled process of emissions during the end-of-life phase and consider the individual characteristics of the products. |
| Answer to specific info request 7:  Please refer to the consultation papers 6399, 6016, 6384 as a reference, as well as: “The Impact of a Potential PFAS Restriction on the Semiconductor Sector” 13th April 2023: The Impact of a Potential PFAS Restriction on the Semiconductor Sector - Semiconductor Industry Association |
| Answer to specific info request 10:  The Annex XV report states that “Shall not be placed on the market in mixtures and articles in a concentration of or above 25ppb for any PFAS and 250ppb for the sum of PFASs (polymeric PFASs excluded from quantification) and 50ppm for PFASs (polymeric PFASs included). However, we think we can’t manage materials and products in this very small amount range, even if chemical and material manufacturer in upstream supply chain, as it is technically unfeasible to distinguish polymer and not-polymer PFAS, and also applied and non-applied PFAS at present. |

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| 9563 | Date:  2023/09/25 22:41  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Wiener Stadtwerke GmbH  Org. country:  Austria  Attachment: | General Comments:  - |
| Answer to specific info request 1:  Applications of fluorinated gases (Annex E.2.8.) - Insulating gas in electrical equipment; - Heat Pumps and electrical chillers; |
| Answer to specific info request 2:  See "Annex XV restriction report" chapter 2.4.3.3.point g) paragraph (xiv). |
| Answer to specific info request 5:  No data available because no alternative gas electrical switchgear with possible PFAS use has yet been installed. |
| Answer to specific info request 7:  With reference to the ""Annex XV restriction report"" Chapter 2.4.3.3.point g) paragraph (xiv) or Table 13 Applications of fluorinated gases (Annex E.2.8.): Even though there are currently PFAS-free products for gas-insulated electrical switchgear up to 145kV on the market, only one manufacturer (Siemens Energy) can currently serve European switchgear needs now and for the next 10-15 years. The competitors (Hitachi Energy, GE Power & Grid) have indicated that there is currently no development strategy for non-PFAS, gas-insulated high-voltage switchgear for the European market. In times of the energy transition and the massive grid expansion required to maximize feed-in capacity from renewables, it would be an economic-political problem to leave the potential switchgear market throughout Europe to just one manufacturer for the next 10-15 years. Transition periods are also not a solution in the medium term - a comprehensive derogation is needed here. Regarding gas-insulated electrical switchgear above 145kV, there are currently no PFAS-free products ready for the market; especially for circuit breakers, there are currently no discernible development steps at this voltage level. Moreover, there are already physical limits in the development of such switchgear, where even market maturity in the next 10-15 years seems unrealistic at present. In general, decarbonising industry and district heating is a major challenge if we are to meet our targets for reducing CO2 emissions, in particular Fit for 55 ones. As a result, the deployment of Heat Pumps (HPs) to decarbonise district heating and industrial heat has been identified as one of the main solutions. The impact of the PFAS ban on Refrigeration, Air Conditioning and Heat Pumps would be twofold: 1) All fluoropolymers fall under the proposed definition in the proposal. These substances such as PTFE, FPM etc are critical to most of the components which makes these systems run efficiently and at best performance. 2) Most F-gases, which are a core part of the full portfolio of refrigerants used on RACHP applications are covered by the proposal. Refrigerants are an essential element for the good functioning of their RACHP components, equipment and systems to heat and cool. In the case of large high-temperature heat pumps, crucial for the decarbonisation of industry and district heating, special refrigerants called Hydro Fluoro Olefines (HFO, e.g. R1234ze) have been developed in order to replace refrigerants according to the F-Gas Regulation (e.g. R134a). These HFOs allow high temperature ranges combined with a high efficiency. They are not ozone-depleting, have a very low GWP and are in case of accidents not so dangerous compared to alternatives like NH3 (toxicity) or propane (flammability and explosion protection). There are already technical solutions to minimise emissions into the atmosphere. A large number of these HFO-based heat pumps with a lifetime of more than 20 years have been recently installed or are in installation. Because the heat pumps are constructed according to the refrigerants’ physical properties, the revamping of the heat pump in order to use natural refrigerants is not possible. It needs to be possible to operate them until the end of their lifetime. The industrial HP market can be divided into 3 categories depending on heat supply temperature (up to the actual limit of 150°C): - Standard HPs providing heat up to 85°C - High-temperature (HT) heat pumps providing heat from 85°C to 100°C - Very high temperature HPs (VHTs) providing heat between 100 to 150°C. The F-Gas Regulation, under ongoing review, mandates the progressive phasing out of fluorinated gases, including HFCs used in refrigeration systems. In order to meet these requirements, European industrials developed few years ago HFC-free solutions, today mature or very close to maturity (in the process of being demonstrated) for these three markets. Most of solutions for the HT and VHT markets (supply temperature > 90°C) are designed to use an HFO-type refrigerant (r1234ze(Z); r1234ze(E); r1233zd(E); r1336mzz(Z)), which belongs to the PFAS family. Manufacturers of industrial HPs have chosen this solution for a number of reasons: Zero ODP, extremely low GWP, limited or zero flammability, non-toxic, optimum performance at target temperatures. For heat pumps providing heat at high or very high level (> 90°C), alternative refrigerants to HFO are still non-existent from a commercial point of view (TRL < TRL 9): the first laboratory demonstrators are under way and the first field demonstrations will see the light of day from 2024/2025 (often using hydrocarbon-type fluids: butane or n-pentane). The use of hydrocarbons will also require time for industries to adapt in order to incorporate these highly flammable refrigerants. The use of water is also an alternative but at laboratory demonstration stage for closed cycles. |
| Answer to specific info request 8:  Use of sliding materials containing PFAS in extinguishing nozzles of circuit breakers in electrical switchgear. Regarding second paragraph of question 8: All operators of gas-insulated high-voltage switchgear >52kV. Regarding third paragraph of question 8: Currently no knowledge about alternatives. |

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| 9564 | Date:  2023/09/25 22:43  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:  Industry or trade association  Org. name:  3D-Printing Equipment Consortium  Org. country:  United States of America  Attachment:    Privacy statement:  Nothing confidential submitted | General Comments:  The comments of the 3-D Printing Equipment Consortium are contained in the non-confidential attachment submitted with this form. The fact that it is Watermarked as 'confidential' can be ignored for the purposes of this consultation. |
| Answer to specific info request 1:  The sector/sub-sector of use being covered by this submission is the supply of 3-D Printing Equipment containing fluoropolymer elements which are essential to the operation of the equipment. |
| Answer to specific info request 2:  The emission profile of fluoropolymers is extremely limited and is addressed within the non-confidential submission. |
| Answer to specific info request 3:  The management of equipment takeback schemes within the industry can ensure that the fluoropolymers in question do not reach the waste stream |
| Answer to specific info request 6:  Despite submissions to the previous two Calls for Evidence, there has been no visible consideration of the use of fluoropolymers in 3-D printing equipment with the only reference to the technology being for two non-polymeric uses. The use of these fluoropolymers is therefore considered a 'missed use'. |
| Answer to specific info request 8:  The difficulties in finding alternatives for the 3-D Printing Equipment industry are documented in the non-confidential submission attached and the socio-economic consequences within the EU are highlighted. |

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| 9565 | Date:  2023/09/25 22:45  Content:  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Hong Kong  Company name confidential:  Yes  Attachment:    <redacted>  Privacy statement:  Attached is a draft paper prepared for submission at a later stage. As such, the shared information is not yet public. | General Comments:  Comments provided in the attachment in SECTION IV. Non-confidential attachment |
| Answer to specific info request 1:  Comments provided in the attachment in SECTION IV. Non-confidential attachment |
| Answer to specific info request 6:  Comments provided in the attachment in SECTION IV. Non-confidential attachment |
| Answer to specific info request 7:  Comments provided in the attachment in SECTION IV. Non-confidential attachment |
| Answer to specific info request 8:  Comments provided in the attachment in SECTION IV. Non-confidential attachment |

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| 9566 | Date:  2023/09/25 22:46  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The confidential information includes economic data of our company as well as specific collaboration partners and alternative products tested in our R&D process. | General Comments:  The electroplating industry uses zinc-nickel alloys as corrosion protection for the highest demands in the automotive-, construction- and many other sectors. The most efficient corrosion protection is achieved by the use of alkaline electrolyte systems, in which, however, many metals do not dissolve or dissolve insufficiently. To complex nickel salts, organic substances based on amines are used. In typical processes, these amines are decomposed at the anode to form cyanides and disruptive degradation products, which negatively affect the deposition process in many ways. These include current efficiency and wastewater treatment. To stop this process, PFAS-based membranes have been used for many years. We ask for an assessment and evaluation of this use as a possible derogation to the proposed restriction. |
| Answer to specific info request 1:  Metal plating and manufacture of metal products (Annex E.2.4.) --> Manufacture of metal products not addressed elsewhere |
| Answer to specific info request 2:  see attached document. |
| Answer to specific info request 5:  see attached document. |
| Answer to specific info request 6:  see attached document. |
| Answer to specific info request 8:  see attached document. |

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| 9567 | Date:  2023/09/25 22:48  Content:  Scope or restriction option analysis  Baseline  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Als Ingenieurdienstleister, Planer und Errichter für den Großanlagenbau spezifizieren und handeln wir verschiedene Werkstoffe und Werkstoffgruppen. Unter anderen finden in unserem Tätigkeitsspektrum nachstehende Halbzeuge und Baugruppen aus Fluorpolymeren-(Werkstoffen) Einsatz: - Fluorpolymere als Dichtungswerkstoffe (Flach-, O-Ring-, Gleitringdichtung, etc.) in verschiedenen Ausrüstungen/Rohrleitungen - Fluorpolymere als Auskleidungswerkstoffe in Pumpen und Rohrleitungswerkstoffen - Fluorpolymere als Membranwerkstoff in Pumpen, Elektrolyseuren Indirekt kommen des Weiteren Fluorpolymere als Kühlmittel oder Additive in Begleitprozessen zur Anwendung, welche jedoch im Tätigkeitsspektrum des Endanwenders/Kunden liegen.  Da das breite Feld des Maschinen- und Anlagenbaus nicht im Beschränkungsbericht in Anhang XV (Tabelle 9) genannten Sektoren aufgelistet ist, wurden nachstehende Bereiche als am ehesten zutreffend ausgewählt - Energy sector (Annex E.2.12.) - Sector as a whole - Petroleum and mining (Annex E.2.15.) - Fluoropolymer applications  Für die genannten Bereiche des Maschinen- und Anlagenbaus sind u.a. Vorgaben aus Gesetzen und Verordnungen zu beachten, um die behördlichen Auflagen zu erfüllen. Unter anderem und abhängig vom Kunden und/oder Hoheitsgebiet sind unterschiedliche Voraussetzungen und Anforderungen (WHG, DGRL, AWSV, TA-Luft) zu berücksichtigen und zu erfüllen. Um diesen Anforderungen gerecht zu werden und die Sicherheit für Mensch und Umwelt zu gewährleisten, werden u.a. die chemisch beständigen und thermisch resistenten Fluorpolymerwerkstoffe (wie z.B. PTFE, PFA, PVDF, FKM) spezifiziert, gehandelt und eingesetzt bzw. in den Großanlagen verbaut. Prozesse sind und werden energetisch so aufgestellt und ausgelegt, dass ein hoher Wirkungsgrad entsteht und somit mit einer hohen Energieeffizienz gearbeitet werden kann. Um dies zu erreichen sind die spezifischen und benannten Fluorpolymeren-Werkstoffe und deren exzellenten Eigenschaften notwendig und unersetzbar bzw. aktuell nicht durch Alternativmaterialien substituierbar. Eine Auswertung verschiedener positiv absolvierter Projekte im Bereich Chlor-Alkali-Elektrolyse ergab einen Einsatz von Fluorpolymeren (als Auskleidungs- und Vollmaterial) in 20% der Ausrüstungspositionen. Diese durch andere Werkstoffe zu substituieren, d.h. durch medienabhängig ähnlich beständige Werkstoffe (wie z.B. Titan Grade 7 oder Grade 2) zu ersetzen, würde eine deutliche Kostenerhöhung erzeugen und die Wirtschaftlichkeit des Gesamtprojektes deutlich in Frage stellen. Um das Argument zu bekräftigen, wurden speziell für eine Ausrüstungsposition ein Kohlenstoffstahl mit PFA-Auskleidung mit einem Titan Grade 2 verglichen und ein Kostenfaktor von +1,48x ermittelt, d.h. bei einem Ausrüstungsgesamtvolumen von 10Mio-€ gehen wir von erhöhten Investition von bis zu 1Mio-€ aus. Ähnlich verhält es sich bei Rohrleitungsmaterial. Hier ist ein Kostenfaktor von +3x ermittelt, zwischen herkömmlich spezifizierten/hergestellten Kohlenstoff-Stahl/PTFE Auskleidung zu substituiertem Titan Grade 7 Werkstoff. Bei Dichtungsmaterialien werden abhängig von, Anforderungen und Prozessparameter etwa 25% (in Summe für ein Standardprojekt 5000Stück Flachdichtung mit Diffusionssperre DN15 bis DN600) Fluorpolymerwerkstoffe, wie PTFE/E-PTFE und PVDF eingesetzt. Diese haben eine hohe Sicherheit für Mensch und Umwelt durch ihre hohe chemische und thermische Beständigkeit gegenüber einer Vielzahl an Medien. Eine Substitution dieser Materialien würde massive Änderungen und Nachteile für andere Bereiche bedeuten, u.a. Einhalten von Verordnungen (TA-Luft), Sicherheit für Mensch und Umwelt (chemische und thermische Beständigkeit), Mehrkosten für ein Wartungs- und Instandhaltungsprogramm (Ressourcenschonender Einsatz von Werkstoffen). Aktuell gibt es oftmals keine Alternativwerkstoffe, die gegenüber entsprechenden Medien beständig sind. Fluorpolymerwerkstoffe sind hier alternativlos. Würden hypothetisch gesehen, die genannten chemisch beständigen und thermisch resistenten Fluorpolymeren-Werkstoffe im Großanlagenbau aufgrund der bekannten und geplanten Beschränkung komplett als Anwendungswerkstoff entfallen, wäre ein bislang nahezu sicherer Prozessbetrieb nicht möglich. Zudem können u.a. Chemieanlagen nicht wirtschaftlich errichtet werden (aufgrund Verschleiß, Wartung- und Instandhaltungskosten, Gefahrenpotential für Mensch und Natur, erhöhter Überwachungsbedarf, etc.) Als weiterer nicht zu vernachlässigender Punkt, wird durch die bekannten Restriktionen für europäische Unternehmen ein nicht zu (unterschätzender) vergleichender Wettbewerbsnachteil geschaffen – gegenüber andere Nationen (u.a. China, Indien) ohne Restriktionen, somit spielen europäische Unternehmen in wirtschaftlichen Sinne nur noch eine untergeordnete Rolle, verbunden mit weiteren sozialökonomischen Faktoren und Folgen. In Europa produzierte Fluorpolymerwerkstoffe besitzen eine höhere Qualität (eigene Erfahrung aus verschiedenen Projekten) und die Herstellung wird besser überwacht (Minimierung Schadstoffbelastung Mitarbeiter, Gesundheitsschutz, etc.).  Uns als Anwender von inerten Fluorpolymeren ist durchaus bekannt, dass bei der Herstellung der überwiegende Teil der Monomere umgesetzt wird, jedoch ein geringer Anteil zurückbleibt und die Umwelt belastet. So landen jährlich tonnenweise nicht umgesetzte Monomere als Abfallprodukt in der Umwelt. Dies ist natürlich nicht akzeptabel und muss beschränkt werden - vor allem in Bereichen, mit geringen Sicherheits- und Umweltaspekten. Für uns als Anwender von Fluorpolymeren im Großanlagenbau gibt es aktuell nur wenig Anwendungen, wo eine Substitution sinnvoll – möglich wäre ist.  Wir aus Großanlagenbauer können die prozentualen Emissionsanteile für unseren Scope, wie folgt einteilen: 0% Emisissionen in der Herstellungsphase (da wir als Endanwender in Erscheinung treten) 0%Emmissionen in der Nutzungsphase 100% Emisissionen in der End-of –Life-Phase (dies ist außerhalb unseres Scopes und wird nicht betrachtet)  Es ist bewusst, dass Maßnahmen hinsichtlich der Reduzierung/Einschränkung von am Markt erhältlichen Fluorpolymeren getroffen werden müssen, aber nicht in Bereichen, wie z.B. den wirtschaftstreibenden Kräften im Maschinen- und Anlagenbau, wo Sicherheit und Stabilität eine ausgesprochene Priorität haben. Unser Anspruch als Ingenieurdienstleister, Planer und Errichter für den Großanlagenbau ist es unseren Kunden und Anwender eine sichere und prozessstabile Anlage zu übergeben, dafür sind u.a. auch Fluorpolymere-Werkstoffe unumgänglich – jedoch nur in Anwendungsbereichen, wo Alternativmaterialien als wirtschaftlichen Zwecken keine geeignete Anwendung finden. |
| Answer to specific info request 1:  Als Ingenieurdienstleister, Planer und Errichter für den Großanlagenbau spezifizieren und handeln wir verschiedene Werkstoffe und Werkstoffgruppen. Unter anderen finden in unserem Tätigkeitsspektrum nachstehende Halbzeuge und Baugruppen aus Fluorpolymeren-(Werkstoffen) Einsatz: - Fluorpolymere als Dichtungswerkstoffe (Flach-, O-Ring-, Gleitringdichtung, etc.) in verschiedenen Ausrüstungen/Rohrleitungen - Fluorpolymere als Auskleidungswerkstoffe in Pumpen und Rohrleitungswerkstoffen - Fluorpolymere als Membranwerkstoff in Pumpen, Elektrolyseuren Indirekt kommen des Weiteren Fluorpolymere als Kühlmittel oder Additive in Begleitprozessen zur Anwendung, welche jedoch im Tätigkeitsspektrum des Endanwenders/Kunden liegen. Da das breite Feld des Maschinen- und Anlagenbaus nicht im Beschränkungsbericht in Anhang XV (Tabelle 9) genannten Sektoren aufgelistet ist, wurden nachstehende Bereiche als am ehesten zutreffend ausgewählt - Energy sector (Annex E.2.12.) - Sector as a whole - Petroleum and mining (Annex E.2.15.) - Fluoropolymer applications Weiterhin siehe SECTION III. Non-confidential comments. |
| Answer to specific info request 2:  Wir aus Großanlagenbauer können die prozentualen Emissionsanteile für unseren Scope, wie folgt einteilen: 0% Emisissionen in der Herstellungsphase (da wir als Endanwender in Erscheinung treten) 0%Emmissionen in der Nutzungsphase 100% Emisissionen in der End-of –Life-Phase (dies ist außerhalb unseres Scopes und wird nicht betrachtet) |
| Answer to specific info request 6:  siehe SECTION III. Non-confidential comments |

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| 9568 | Date:  2023/09/25 22:54  Content:  Scope or restriction option analysis  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Embraer S.A.  Org. country:  Brazil  Attachment: | General Comments:  Embraer S.A. appreciates the opportunity to offer the attached comments for your consideration regarding the Per- and polyfluoroalkyl substances (PFAS). |
| Answer to specific info request 1:  Fire suppressants, especially applicable to civil aviation. |
| Answer to specific info request 5:  As described in the attached document, the proposed derogation is not viable for the aviation industry. Nevertheless, emissions of fire extinguishers in aviation are significantly low due to the rare nature of fire events onboard of an aircraft. |
| Answer to specific info request 6:  Since the current fire extinguisher used in aviation (halon) had to be replaced due to the Montreal Protocol, no technically feasible alternatives were found for almost three decades. The impacts of prohibiting current fire extinguishers due to the PFAS restrictions would result in no fire extinguisher agents/systems available to allow aircraft operations worldwide. |
| Answer to specific info request 7:  ECHA’s ANNEX XV RESTRICTION REPORT proposes a limited derogation to use PFAS in fire extinguisher systems for aviation, until 13.5 years after entry into force. This proposal is not practical under aviation industry perspective, since no new alternatives to halon, capable of complying with either the Montreal Protocol and the PFAS restriction, could be found for each specific application and meeting their specific safety minimum performance standards in this period of time. In fact, much more time has been spent to find the existing alternatives for halon replacement; and the few ones found to be viable up to now are classified as PFAS in the majority. ECHA’s proposal, as is, would have a global impact to society and aviation industry, either in fire extinguishers currently used or in halon replacement systems under development. |

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| 9569 | Date:  2023/09/25 23:04  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Please keep the documents confidential as they contain sensitive data and company information | General Comments:  - |

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| 9570 | Date:  2023/09/25 23:09  Content:  Scope or restriction option analysis  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  European Federation for Medicinal Chemistry and Chemical Biology (EFMC)  Org. country:  Switzerland | General Comments:  PFAS include a vast range of fluoroalkyl materials, ranging from simple fluorinated reagents and starting materials used in drug discovery and development (including the synthesis of active pharmaceutical ingredients), to thermoplastic polymers found in laboratory commodities such as stirring bars or O-rings. The entire ban of these materials can lead to major disruptions in all research, development, and innovation activities related to medicinal chemistry and chemical biology. Ultimately, it can have long-term implications on the innovation potential of EU research. Importantly, there are currently a significant number of compounds in clinical use or in Phase III of clinical trials (the last stage before approval and marketing) containing fluorinated groups such as CF3 and CF2, or combination of both, in their structure. These are life-saving compounds, and thus a transition period should be considered to enable a detailed analysis of the socio-economic impacts of a ban in the short-term and to find efficient, safe and economically viable alternatives. |

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| 9571 | Date:  2023/09/25 23:10  Content:  Information on benefits  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  Mit den folgenden Informationen möchten wir den Vorschlag zur Beschränkung von Per- und Polyfluoralkylsubstanzen (PFAS) kommentieren. Wir sind der Ansicht, dass die vorgeschlagenen Ausnahmeregelungen unter Absatz 5 des Vorschlags die weitere Verwendung (Schmierstoffe unter "harsh conditions") in vielen Industriezweigen ermöglichen könnten. Auf Grund der bisher fehlenden Alternativ-Produkten und den langen Freigabeprozessen bis zur Genehmigung des Einsatzes neuer Stoffe und Komponenten (z.B. in der Luftfahrt, im Automobilbereich oder in der Medizintechnik) empfehlen wir jedoch eine vorläufige, generelle Ausnahme und eine Prüfung, ob Alternativen zur Verfügung stehen, nach 5 bzw. 12 Jahren. Eine einfache Substitution von PFPE/PTFE basierten Schmierstoffen für bestimmte Anwendungen ist nicht möglich. Es wurden bereits viele Anstrengungen unternommen, diese hochpreisigen Schmierstoffe zu ersetzen; bisher ohne Erfolg. Ein mögliches Verbot von PFPE/PTFE-Schmierstoffen widerspricht gleichzeitig den aktuellen Nachhaltigkeitsbestrebungen (geringere Lebensdauer von Ersatzschmierstoffen und Komponenten; somit erhöhte CO2-Emissionen). Bei kritischen Stoffen (Sauerstoff/H2 etc.) führt der Austausch von inerten PFPE/PTFE-Schmierstoffen zu Sicherheitsrisiken. Bei der Herstellung von Schmierstoffen kommt "high-end" Maschinentechnik zum Einsatz. Derzeitige Dichtungsmaterialien basieren auf Fluorpolymerbasis (z.B. FKM); diese sind inert sowohl gegenüber polare als auch unpolare Medien, welche in Schmierstoffen zum Einsatz kommen. Des Weiteren schließen wir uns den Stellungnahmen des europäischen Schmierstoffverbandes (UEIL), des europäischen Europäische Automobilherstellerverbandes (ACEA), des technischen Verbandes der europäischen Schmierstoffindustrie (ATIEL) und dem Verband Schmierstoff-Industrie e. V. (VSI) an. |
| Answer to specific info request 1:  Lubricants Sealings |
| Answer to specific info request 3:  Please see the following studies: Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas [Aleksandrov et al, 2019] Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions [Gehrmann et al, 2023] |

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| 9572 | Date:  2023/09/25 23:09  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Baseline  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  FluorTex GmbH, Polymer Technology  Org. country:  Germany  Attachment: | General Comments:  The concerned dossier submitted by BAuA and four other governmental organizations from Sweden, the Netherlands, Denmark and Norway concerning the restriction procedure for so-called PFAS was published by the European Chemicals Agency (ECHA) on the 07th Feb. 2023.  The restriction proposal also concerns all fluoropolymers, which are included in the large group of PFASs to be regulated via the definition of the presence of fluorinated carbon atoms (CF2 and CF3).  According to the submission, the background of this proposed regulation, which is intended to ban the manufacturing, placing on the market as well as the use of fluoropolymers, is the persistence of these substances, which is assessed as the "key hazardous property" in section 1.1.4 of the hazard assessment in the Annex XV Report.  The other potential hazards do not concern the fluoropolymers because they are not volatile, not mobile, not bioaccumulative, not toxic and no endocrine disruptors.  Thus, persistence is the main concern for regulation of these polymers (see Section 1.1.4.2. Annex XV Restriction Report "persistence as the core concern").  In order to be able to enforce an appropriate regulation also for fluoropolymers, alternatives were already asked for in the Calls for Evidence, which were intended to serve for the collection of information for the preparation of the dossier, and some information providers (stakeholders) also named some.  The alternatives for fluoropolymers mentioned in the dossier are essentially non-fluorinated polymers such as polyethylene (PE), polyetheretherketone (PEEK), or in the case of elastomers, ethylene-propylene-diene (monomer) rubber (EPDM).  In the restriction proposal, these polymers indicated as alternatives are not subjected at any point to a necessary hazard assessment, which is, however, already absolutely necessary in the preparation of such a dossier in order to determine whether alternatives may be named as such at all.  In Annex E, Appendix E2, with regard to all non-fluorinated polymers mentioned, "No data found" is stated for the PBT / vPvB assessment, or "Not sufficient data available for evaluation" is stated for Additional Information - which clearly does not correspond to an apropriate risk assessment, although sufficient meaningful data on this are publicly available. Please refer to the attachment in "SECTION IV. Non-confidential attachments", where you can clearly see that polymers in general are very persistent and even polymers considered as "bio degradable" in humus composting are very persistent in the sense of the definitions in Annex XIII REACH . If you would have any doubts about the persistence of all plastics, as synthetic materials, please see the publications on persistent plastics in the world's oceans, which certainly do not lead to a PBT / vPvB assessment of "No data found".  Thus, demonstrably persistent polymers are given as alternatives to fluorinated polymers in this ANNEX XV Dossier, which leads to a nonsense of the whole process.  In addition, non-fluorinated alternatives are specified, although they do not match the properties of fluoropolymers, resulting in much higher wear and thus higher consumption of non-fluorinated polymers, which, as persistent materials, increase the environmental impact. It should be noted that fluorinated polymers do not have a higher end-of-life impact than conventional polymers because they do not decompose into hazardous substances and do not release hazardous substances when disposed off as intended.  This is regulated separately in legal acts concerning waste management. Otherwise, substances such as dioxins or e.g. hydrochloric acid would still be generated and released, due to the uncontrolled incineration of municipal waste, or PVC that you listed as an alternative to fluoropolymers in Appendix E2. |
| Answer to specific info request 1:  all sectors and (sub-)uses are concerned |
| Answer to specific info request 2:  fluoropolymers to not have higher emissions in the end-of-life phase, than non-fluorinated polymers - EU Waste Management Regulations are in force (do not double-regulate!) |
| Answer to specific info request 3:  fluoropolymers to not have higher emissions in the end-of-life phase, than non-fluorinated polymers - EU Waste Management Regulations are in force (do not double-regulate!) |
| Answer to specific info request 5:  Emissions of fluorinated production aids play and important role in this restriction process. However, the substances relying on PFAS emulsifiers can be produced in closed loop systems, which is also what is demanded from the scientific circles you mentioned in the dossier: "The system would have to be changed so that persistent substances are not allowed to be used in open applications, but only in closed systems." (Prof. Martin Scheringer, ETH Zurich, 31.07.2023). Derogations make no sense, as long as the production of needed fluoropolymers (PTFE, PVDF and FKM) with fluorinated production aids will be regulated. Example: what sense does a 13,5 years derogation for a stent covering with an expanded PTFE membrane make, if the polymer can't be produced any more from 18 months after EiF, because fluorinated processing aids must not be used any more!? |
| Answer to specific info request 6:  missing uses have already been adressed to Mrs. Averbeck and Mr. Dannenberg during a web-meeting on the 12th of Jan. 2022 - unfortunately without success. |

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| 9573 | Date:  2023/09/25 23:13  Content:  Information on alternatives  Information on benefits  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes | General Comments:  Our company is active in the manufacturing of elastomeric diaphragm using polymeric PFAS, namely FKM, FFKM and fluorosilicones FVMQ. Since fluoropolymers are the key component to some of our products, the PFAS content of our finished articles is rather high. Fluoropolymers, due to their chemical structure, exhibit a unique combination of properties, that can’t be matched by any other type of more conventional and more cost-effective polymer or material. They are the ultimate choice when the following requirements come from our customer base: • High fluid resistance (fuels, lubricants, water, steam, complex chemical mixtures) • High temperature resistance (200°C or in excess) • Low permeability to gases and liquids (natural gas, hydrogen, fuels, etc.) • Resistance to cleaning and sterilization media (acid, bases, steam, ethylene oxide, etc.) • High purity (low metal content, low leachables/extractables, low particle generation) • Resistance to different type of gaseous plasma  We manufacture FKM, VMQ and FFKM diaphragms that are used in different types of transportation means, both for civil and military applications, e.g. trucks, heavy duty vehicles, ships and aircrafts; the reason of their widespread usage in this sector is the unique combination of low temperature sealing ability (for FVMQ and some types of FKM), high temperature stability (products close to the aircraft turbines can exceed 300°C especially during take-off) and inertness in fuels, lubricants and hydraulic fluids. Most of our fluoropolymer based products were designed to increase overall transportation efficiency (lower fuel consumption, lower CO2 emissions, reduced release of particulates and NOx from combustion engines). Most of the materials are specified under US military standards (MIL specs), Aerospace Material Specifications (AMS) established by the Society of Automotive Engineers (SAE), British Ministry of Defence specs (DTD specs), British Defence Standard 02-337, French aerospace standards, such as NFL 17 106, etc.. FKM and FFKM products are also widely used in chemical process industry as safety critical components in pumps, compressors, mechanical seals, flanges, etc. for their unmatched combination of thermal stability and chemical inertness in complex chemical mixtures. They enable the global chemical industry to operate in safe conditions, reducing fugitive emission to ground, air and water as well as minimizing exposure of emissions to facility staff. Their long term reliability allows to increase both mean time between failures (MTBF) and mean time between repairs (MTBR), making the process industry safer and reducing its operating costs at the same time. Fluoropolymer based seals are also one of the key enablers for the implementation of desirable future technologies, such as industry decarbonization and hydrogen economy.  FKM, FEPM and FFKM are widely specified in oil & gas applications (drilling, completion and production) by a number of service companies (BH, Schlumberger, Weatherford, Halliburton, etc.) as well as by the oil majors (Shell, Total, Saudi Aramco, Exxon, BP, etc.). Moreover fluoroelastomer seals are also getting more and more attention in the so-called alternative energy business, such as hydrogen storage and transportation due to their low hydrogen permeation rate as well as hydrogen manufacturing in electrolysers, due to their combined temperature and chemical resistance. However, in the short to medium term, most of the global hydrogen production will still rely on steam reforming of natural gas followed by carbon capture (CCUS), i.e. the so-called blue hydrogen process; exploration and exploitation of gas deposits with high concentrations (up to 40%) of H2S (sour gas) can only be safely conducted when using special types of fluoroelastomer diaphragms. FKM and FFKM based diaphragms are also being developed for future applications in deep geothermal wells where high temperature water and steam (typically more than 220°C, in some cases between 250 and 300°C) are extracted from stimulated fractured rocks. No other sealing material is available to withstand water exposure at such operating temperatures.  Semiconductor applications make use of significant quantities of FKM and FFKM; most of the requirements are specified by the single customers according to their specific process conditions. The main reasons for such an extensive use of fluoropolymers in semiconductor manufacturing process chambers are resistance to plasma (in the etch and deposition processes as well as in plasma chamber cleaning processes), high purity (low release of organic and metallic contaminants along with low particle shedding) as well as high temperature resistance (some deposition processes, such as PECVD, operate in excess of 250°C). FKM and FFKM diaphragms are also safety critical components of ancillary equipment (such as vacuum pumps) and in the subfab effluent treatment systems that are designed to abate highly toxic gases and that usually operate at high temperatures (above 250°C) to avoid condensation and the formation of potentially dangerous deposits in the ductwork.  As a company, we also have a well-defined portfolio of food contact materials based on FKM and FFKM; they are widely used in food and beverage processing equipment, such as pumps. Their inherent thermal and chemical stability make them the only technical solution for high demanding applications like SIP (steam-in-place) and CIP (clean-in-place) processes for cleaning and sterilization of equipment, that make use of a combination of steam, acids and bases. Moreover FKM and FFKM are well known for their intrinsic higher level of purity compared to other more conventional elastomers, thus minimizing the risk of contaminating the processed food. Our Food Contact Materials based on FKM and FFKM have been extensively tested in terms of overall migration into food simulants (following US FDA regulations 21CFR 177.2600 and 21CFR 177.2400 and German BfR recommendation XXI/1), meeting the limits imposed by the various regulations. Some of them were also submitted to USP Class VI 87 and 88 testing, showing lack of cytotoxicity both in vitro and in vivo testing. Their usage has been constantly growing over the last few years because of the implementation of stricter regulations to defend consumer’s health (lower migration into the food streams) and of the use of more severe conditions for cleaning and sterilization of food processing equipment and plants. Fluoropolymers are a key enabler for this; in case of restrictions in the use of fluoropolymers, no sealing material would be available to meet these market needs. For the same reasons above, FKM and FFKM based products are used in the manufacturing of many active pharmaceutical ingredients.  We firmly believe that the proposed restriction stemmed from general concerns about some non-polymeric PFAS toxic effects on humans, in combination with their potential to bioaccumulate, to be persistent and/or mobile in the environment. It is therefore imperative for the European authorities to restrict the usage of these substances to protect the citizen’s health and the environment. As mentioned above, most fluoropolymers are biocompatible; for this reason, a wide range of fluoropolymers based articles has been used for decades in medical devices and in implantable devices thus intrinsically disputing the conclusion that fluoropolymer PFAS pose unacceptable risks to human health. We strongly believe that the restriction proposal should differentiate between the various types of PFAS on the basis of their chemical composition and toxicological profile, manufacturing method and their particular uses. All PFAS are not the same and we therefore believe that a “one size fits all” regulation is simply too broad.  We believe that a total ban on fluoropolymers is not proportionate. Given their benign hazard profile, an unlimited general derogation / exemption for industrial applications of fluoropolymers and fluorosilicones should be provided in the proposal. Together with the derogation for the polymers, a derogation for all the needed intermediates (fluorinated monomers, fluorinated chain transfer agents, fluorinated cross-linking agents, etc.) should be granted to allow manufacturing of the derogated polymers within the EU borders. This is not taken into consideration in the current restriction proposal and is a serious contradiction that needs to be resolved before the entry into force; as a matter of fact, the proposal allows for some specific time limited derogations for fluoropolymers but it fails to make provision for their manufacturing by derogating the necessary ingredients for the manufacturing of said fluoropolymers.  We advocate for a full unlimited derogation / exemption for fluoropolymers in their industrial applications; we think that this is justified by the fact that fluoropolymers are key enablers for a lot of critical existing industrial applications (as stated above, transportation, defence, chemical process industry, energy, semiconductor, food processing, etc.) as well as of many others under development. If we consider alternative natural or synthetic elastomers, we can list the following with the corresponding characteristics.   Material type Min T (°C) Max T (°C) Good fluid resistance Poor fluid resistance Purity NBR -50 120 Hydrocarbons Polar solvents, ozone Low HNBR -50 175 Hydrocarbons, ozone Low EPDM -50 150 Water, steam, ozone Hydrocarbons Low VMQ -60 180 Water, steam, ozone Hydrocarbons High AEM -40 180 Hydrocarbons, ozone Low ACM -25 170 Hydrocarbons, ozone Polar solvents, water Low CSM -30 150 Hydrocarbons, water, ozone Polar solvents Low CR -30 100 Hydrocarbons, water, ozone Polar solvents Low ECO -40 135 Hydrocarbons, water, ozone Polar solvents Low IIR -40 110 Water Hydrocarbons Low SBR -50 100 Water Hydrocarbons, ozone Low NR -60 80 Water Hydrocarbons, ozone Low FKM -50 240 Hydrocarbons, steam, sour gases Amines, polar solvents Medium to high FEPM -5 220 Steam, amines, sour gases Polar solvents, aromatics Medium FFKM -40 327 All None High FVMQ -60 200 Water, steam, ozone, hydrocarbons Medium  From the table above, it is evident that no other non-fluorinated elastomer can effectively and safely work at temperatures exceeding 180°C and in a combination of aggressive fluids.  The dossier submitters state that a move away from using fluoropolymers to alternative materials in many applications can be made. We don’t share the same view; as a matter of fact, there are no alternatives that can deliver the same combination of functionality and performance. Due to their inherent higher cost, fluoropolymers are a necessity, not a choice for all their industrial applications. The lack of recognized alternatives could instead open the door for regrettable substitution to alternatives that do not perform at the same specification as fluoropolymers, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety standards. Fluoropolymers underpin the implementation of key EU initiatives and UN climate objectives such as the European Green Deal, the EU Chips Act, the EU Hydrogen Strategy and EU Sustainable and Smart Mobility Strategy. The proposed restriction creates general uncertainty that would undermine investment decisions and innovation in these and other important EU ambitions. Without fluoropolymers all these initiatives won’t be possible. EU dependence on foreign semiconductor technology will dramatically increase and all green energy and transportation initiatives will be seriously undermined. At the same time, EU based businesses won’t be able to compete at plane level field against non-EU businesses that will still be allowed to use fluoropolymers.  Overall, the restriction proposal significantly underestimates the breadth of use and importance of fluoropolymers use in key applications, their benefits to society, their instrumental role with regards to the EU ambitions in climate and energy and economic growth, enabling quality of life for European citizens as well as the lack of viable alternatives to replace them. As an example, there are many industrial sectors in which fluoropolymers are used today that are not mentioned in the proposed restriction, such as the chemical process industry including chloro-alkali processes, batteries for EV, geothermal energy capture, water and atmosphere purification, water electrolysis, energy/hydrogen storage, applications in pharmaceutical manufacturing equipment, military & defence and high-end niche applications. These sectors, not included in the time limited derogations, are potentially targeted for immediate ban (18 months after entry into force of the restriction).  We can also conclude that not all PFAS have been fully risk assessed in the proposal and that therefore a precautionary approach that extends the risk assessment of some PFAS to the whole category of PFAS (including fluoropolymers) is simply disproportionate, unjustified and counterproductive.  Furthermore, with regards to the time limited proposed and potential derogations, the proposal does not seem to take into due account that many applications may have to be redesigned from the bottom up or that, in order to meet stringent standards requirements (e.g. safety standards), testing on potential alternatives will need to be undertaken to ensure suitability. In some cases (for instance aerospace and petroleum industry) the full requalification of alternatives can take up to 20 years. Therefore the derogation time must be reasonable and must consider the necessary innovation time. We therefore encourage the ECHA committees to take into consideration stakeholder input to develop an opinion that offers realistic and well substantiated periods of derogation. |
| Answer to specific info request 1:  Food contact materials and packaging (Annex E.2.3.) Medical devices (Annex E.2.9.) : Membranes used for venting of medical devices Transport (Annex E.2.10.) Petroleum and mining (Annex E.2.15.) Energy sector (Annex E.2.12.) |
| Answer to specific info request 6:  We regret that diaphragms devices (regulators, pumps, valves…) were not listed in the restriction proposal, despite their mission-critical applications in most EU key industrial sectors. We would like to reiterate that diaphragms devices using fluoropolymers (fluoroplastics, fluoroelastomers) are irreplaceable in certain industries as they ensure the safety and reliability of gas, liquid and powders processes and in broader terms of many industrial infrastructures. |

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| 9574 | Date:  2023/09/25 23:16  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  PFAS.BIO Inc  Org. country:  United States of America | General Comments:  PFAS molecules have become the most pressing health and environmental issue of our time. Arguably greater even than carbon emissions which though serious do not pose the same level of immediate health and environmental risks that PFAS pollution does. Still there are better ways to approach this issue than how has been proposed.  We present 3 points to be taken into consideration below.  1) “Whatever mess technology gets us into, technology can get us out of”. This is not to say that we should knowingly continue our destructive and polluting ways with the expectation that we will find a solution for reckless behavior through technology. It is to say though that there are dozens to hundreds of intelligent and well funded groups working on solutions specifically to remediate PFAS pollution and find alternatives. Right now we are in the dead zone where we know the dangers posed by some PFAS molecules but do not have any easy, inexpensive commercially scalable solutions to remediate the damage they have caused. There are however a number of very different technologies in development for helping humanity against PBT PFAS. a. Remediation Technologies i. Supercritical Water – Battelle from the United States is using water under high pressure that is heated to 370 C. At the temperatures and pressures these systems operate oxidation is able to happen that breaks the pfas molecules down to their mineral components. This method has a draw back of requiring lots of energy, however a big pro is that it should be able to break the pfas molecules down to mineral level and is scalable. ii. Bioremediation - A Princeton University group in USA is using bacteria that has been shown to effectively breakdown PFOA and PFOS as well other strains of bacteria being worked with for other PBT PFAS. These should be able to be used directly in the soil and waters to clean them. iii. Chemical and Physical means –A University of Illinois group is working to use UV with catalysts to break PFAS molecules down or using ultrasound to utilize cavitation to destroy PFAS molecules as examples. b. Filtration Technologies i. A US company Cyclopure is using technology developed at University of Illinois to make highly effective pfas filters that can be used at home or scaled to work at the government level. There are many more groups working to develop solutions for cleaning up the pollution caused by PBT PFAS. 2) We don’t stereotype people so why do we stereotype molecules? a. Of the 10,000 plus PFAS molecules only about 100 pose serious risk and are classified as PBTs. To lump in all PFAS molecules together because of a few bad actors would be to stereotype. One would not lump in all Algerians as terrorists because of the actions of a few. Why would we lump in all PFAS molecules as needing to be banned because of the danger posed by a few of them? Unless ECHA can show that a molecule poses danger to health and environment they should not be banned. There are PFAS molecules providing humanity with life saving pharmaceuticals, advancing our computing and microchip capabilities, helping to explore space, allowing our plumbing and electrical infrastructure to work, putting out fires, keeping the temperature in buildings and refrigerators under control and are in all our cellphones. These beneficial and hard working PFAS have not done anything wrong yet they are being treated in the same way as the molecular terrorists that are PBTs. 3) “Carrots are more effective than sticks” a. A tax on importation or usage of PFAS molecules to cover the cost of cleanups and funding research and development into new technologies would be a much better solution that can help European economy and innovation by funneling the money towards development of clean up technologies and also into PFAS alternatives for groups based in the EU. With the goal that it will be EU companies and groups leading the way in our first point above. b. Threatening to ban something when there are no viable alternatives known creates distrust and panic in the long term viability of European industrial sectors as they look to compete against USA, China, India and other economic zones. |

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| 9575 | Date:  2023/09/25 23:20  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United Kingdom  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Commercially sensitive data are provided to support the SEAC review, including information on production processes and business strategy. | General Comments:  In addition to information provided below with respect to Specific Information Requests, we support responses previously submitted by Cefic, Hydrogen Europe, the International Platinum Group Metals Association and the European Precious Metals Federation. |
| Answer to specific info request 1:  Please see confidential attachment |
| Answer to specific info request 5:  Please see confidential attachment |
| Answer to specific info request 7:  Please see confidential attachment |