**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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| 9576 | Date:  2023/09/25 23:23  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  VDMA Waste Treatment and Recycling Technologies  Org. country:  Germany | General Comments:  So far, no derogation has been made for waste treatment and recycling technologies. However, these are crucial for enabeling the circular economy and should thus have an exemption. |
| Answer to specific info request 2:  The bachelor thesis of Emine Sürmeli at Hochschule Rhein Main, summerized different end of life options for Flourpolymers. Also we can provide contact with a company how actually does recycling PTFE. |
| Answer to specific info request 4:  To our knowledge it is currently not possible to estimate the impact the restriction would have on the recycling process and in how far the proposed concentration limits would be met. As far as we know, currently PFAS are not meassured in waste streams. Thus it is not clear up to which amount PFAS are included in waste streams. Recycler currently do not have any testing option for PFAS. |
| Answer to specific info request 6:  In the waste treatment and recycling technology sector PFAS, more specifically Fluorpolymers may be used in the following examples. The list is non-exhaustiv: - Air conditioning units in mobile vehicles - Seals e.g. in engines - Cable sheathing in machinery and equipment where it must be fire retardant - Insulations/dampers - In components e.g. hydraulic components, fittings, pumps, bearing bushings, electronics, sensors - In production e.g. as PTFE heating plates for plastic welding - Baffle plates Other applications and/or components may be effected as well. There is no clear overview of the PFAS application in waste treatment and recycling technologies. |

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| 9577 | Date:  2023/09/25 23:32  Content:  Description of analytical methods  Type:  Individual  Country:  Sweden  Attachment:    <redacted> | General Comments:  - |
| Answer to specific info request 1:  The proposed analytical techniques, combustion ion chromatography (CIC)-based total fluorine (TF) determination together with pyrolysis-gas chromatography-mass spectrometry (pyr-GC/MS) are believed to be relevant for most sectors and sub-uses to quantify and verify presence of polymeric PFAS in materials and products. |
| Answer to specific info request 10:  RISE Research Institutes of Sweden has coordinated the POPFREE Industry project, and collaborated with partners, especially with the Department of Environmental Science at Stockholm University in developing analytical methods to screen products for PFAS-content with focus on polymeric PFAS. Combustion ion chromatography (CIC)-based total fluorine (TF) determination together with pyrolysis-gas chromatography-mass spectrometry (Pyr-GC/MS) have successfully been used for quantification and identification of polymeric PFAS in a wide range of product samples. The combination of these two methods offers a promising strategy for enforcing the 50 ppm concentration limit including polymeric PFAS in materials and products in the class-wide PFAS restriction. Compared to methods that employ extraction before analysis, both CIC and pyr-GC/MS are based on direct thermal breakdown of samples which makes them faster and better suited for detection of polymers. The higher detection limits associated with CIC and pyr-GC/MS make these techniques unsuitable for enforcing the 25 ppb/250 ppb individual PFAS limits that require a more sensitive, targeted approach. Over 50 consumer product samples have been analysed. Products that are known to contain intentionally added fluoropolymers or side-chain fluorinated polymers display levels between 200 ppm and 630 000 ppm (mg/kg or µg/g). The latter high concentrations are obtained when analysing for example a PTFE non-stick coating or dental floss made of PTFE. Highly fluorinated ski wax measure 57 000 ppm, PTFE as an additive in the plastic measured around 1500 ppm (corresponds to 0.15 w% in the plastic). In know PFAS-treated textiles typical fluorine concentrations are in the range 200 – 1600 ppm. Interestingly all textile with known PFAS-free treatments measured less than 50 ppm indicating that the 50 ppm total fluorine concentration is a realistic value separating the PFAS-free from PFAS-containing textiles. Also, other products that were known to be PFAS-free measured a total fluorine concentration under 50 ppm. To confirm that the fluorine was organic in nature, and deduce structure, a qualitative pyrolysis-gas chromatography-mass spectrometry (pyr-GC/MS) method was validated using a suite of reference materials. When applied to samples with unknown PFAS content, the method was successful at identifying polytetrafluoroethylene in cookware, dental products, and electronics at concentrations as little as, both when being the main ingredient and as an additive in the plastic at 0.1-0.2 wt%. It was also possible to distinguish between 3 different side-chain fluorinated polymers in textiles. RISE has employed these two methods in contract work with industry partners. In two projects the samples were textiles. As a first step all textiles were screened for total fluorine and the samples with a total fluorine concentration over 50 ppm were analysed with pyr-GC/MS. The presence of side-chain fluorinated polymers (SFP) was confirmed in all those samples. Most samples contained a C6-SFP but we could also find a couple of samples that contained C8-SFP. In another customer project cookware products were analysed. The total fluorine was less than 50 ppm and we could not detect any fluoropolymer with pyr-GC/MS. This product was designed to be PFAS-free. For some cookware products and electronic samples such as heat protective coatings/sheets in a coffee maker (and possibly in other household equipment that we have not yet analysed) and cables we measure a total fluorine concentration between 70 – 3000 ppm, but we cannot conclude the presence of PFAS with pyr-GC/MS. Some further investigation indicate that these products may contain the inorganic pigment mica, an inorganic pigment/filler that is commonly used in cookware to provide pearlescent aesthetics and for heat protection in high-temperature applications. Thus, for future compliance pyr-GC/MS is a suitable technique to verify the origin of the quantified fluorine. Although many product samples have been analysed there are more to be tested and further optimization that could be done. Further method development is planned to be elaborated in PARC - receiving funding from the European Union’s Horizon Europe research and innovation programme under Grant Agreement No 101057014, project 6.4.3.b 2023-2026. The higher detection limits associated with CIC and pyr-GC/MS make these techniques unsuitable for enforcing individual PFAS limits (25 ppb/250 ppb), which require a more targeted approach with for example LC-MS/MS. The 25 ppb limit is reasonable for individual PFAS. What has to be decided in the final restriction is how many and which PFAS substances that should be analysed for this 250 ppm of total PFAS, but since many products and articles contain polymeric PFAS, the total fluorine detection is more appropriate as a first screening. For example, in a textile sample that was analysed we detected a concentration of 1500 ppm total fluorine (and a C6-SFP was confirmed with pyr-GC/MS) and when analysing the same sample with target analysis of 24 individual PFAS substances, the total sum was 11 ppb. After oxidation and TOPA (total oxidizable precurssor assay) the total sum had increased to 3000 ppb, but still way far from the levels obtained with total fluorine. We have received textile samples where other labs claimed that they did not detect PFAS, while with our combination of methods we could see that PFAS were present (the combination of CIC and pyr-GC/MS). This underlines that extraction before combustion (such as extractable organic fluorine EOF or TOF, where an extraction has been done) is not suitable for detecting polymeric PFAS in samples and products. Methods based on direct thermal breakdown of samples are faster and better suited for detection of polymers. Since the inorganic and organic (PFAS) source of the quantified fluorine from CIC can’t be separated, it is important to stick with the phrase Total Fluorine with the 50 ppm concentration level in the final restriction and NOT change to Total Organic Fluorine. The presence of organic fluorine can be confirmed in the second step with pyr-GC/MS. A manuscript that very soon will be submitted to a scientific journal and a poster that was presented at the Fluoros 2023 conference in Idstein 30 August – 1 September are submitted in the ECHA portal as attachments to this consultation. |

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| 9578 | Date:  2023/09/25 23:37  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United States of America  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The information contained in this attachment divulges commercial and market information, including intellectual property this is confidential to our company. | General Comments:  Please see confidential attachment. |
| Answer to specific info request 1:  Technical textiles, including medical and protective apparel end uses. |

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| 9579 | Date:  2023/09/25 23:40  Content:  Scope or restriction option analysis  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  <redacted>  Org. country:  United States of America  Company name confidential:  Yes  Attachment: | General Comments:  ISEA asks for a time-unlimited derogation on PPE, firefighter turn-out gear, and gas detection equipment. |
| Answer to specific info request 1:  please see attached comments. |
| Answer to specific info request 2:  Please see attached comments. |
| Answer to specific info request 3:  Please see attached comments. |
| Answer to specific info request 5:  ISEA asks for a time-unlimited derogation period for PPE, professional firefighter gear and for gas detection equipment. |
| Answer to specific info request 6:  Please see attached comments. |
| Answer to specific info request 7:  Please see attached comments. |
| Answer to specific info request 9:  Please see attached comments. |
| Answer to specific info request 10:  Please see attached comments. |

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| 9580 | Date:  2023/09/25 23:39  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Protection of our commercial interests, including intellectual property (confidential business information). | General Comments:  - |

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| 9581 | Date:  2023/09/25 23:40  Content:  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Spain  Company name confidential:  Yes | General Comments:  Short time to adapt to the market. |
| Answer to specific info request 8:  Domestic air conditioners with R-32 have been available in a more or less affordable way since 2015 in the Spanish market. After 8 years, this equipment does not represent even 10% of the total stock of this type of equipment. We are debating the banning of a product in a period of time that is absolutely impossible to comply with. The OEMS need time to develop alternatives with other types of gases, and the market needs time for equipment to be replaced as the fleet ages. The timeframe needs to be manageable to avoid meeting the impossible and leading to the emergence of an uncontrolled black market, as has happened in the past with over-ambitious proposals. |

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| 9582 | Date:  2023/09/25 23:46  Content:  Scope or restriction option analysis  Information on benefits  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Trade union  Org. name:  IGBCE  Org. country:  Germany | General Comments:  IGBCE - Industriegewerkschaft Bergbau, Chemie, Energie - supports the goals of the EU Green Deal and the environmental and climate protection targets it sets out, and is committed to achieving a sustainable and equitable transformation. This includes developing a balanced and equitable approach to the regulation of per- and polyfluoroalkyl substances (PFAS). Of paramount importance is to consider environmental, occupational and health protection while maintaining innovation and competitiveness. A comprehensive ban would have a massive impact on the German and European industrial base. Preserving value chains in Germany and Europe not only safeguards jobs and locations, but also technology leadership in transformation industries. In addition, dependence on other regions of the world is reduced, which is of great importance especially against the backdrop of changing geopolitical conditions.  The IGBCE represents the interests of around 580,000 employees in Germany. To this end, the IGBCE engages in dialog with employers and politicians in a spirit of social partnership. Because only constructive cooperation can set the course for the future.  The members of the IGBCE are employed in a wide variety of industries in Germany. They develop and manufacture the future technologies and products needed to achieve the European Union's climate targets. Many of these necessary products are only possible because of the unique properties of PFAS materials and thus form the basis of the industry's transformation. The critical infrastructure of energy generation, transportation and storage, as well as the chemical, pharmaceutical and electrical industries, currently function only with products containing PFAS. They are also found in many large-scale industrial facilities, medical devices, semiconductors, electrolyzers, pharmaceuticals and high-purity packaging. To do this, the materials used must withstand extreme temperatures, corrosive acids and be durable for safety-related reasons. However, these special properties of PFAS substances can also lead to negative effects for the environment and humans. Therefore, not only the input into the environment has to be stopped, but also the intensive research and development of alternatives is of great importance. However, this requires a lot of time if similar processes are used as a comparison to find substitutes with the same technical properties. The proposed deadlines in the EU restriction proposal are generally too short and need to be adjusted and exceptions granted in certain areas of application.  The IGBCE is committed to a sustainable and responsible approach to chemicals that makes production safe and prevents their release into the environment. Also against the background of occupational health and safety, there is a need for a targeted strategy in dealing with PFAS. This includes more targeted monitoring and better control so that potential inputs into the environment are prevented and no further accumulation takes place in the food chain.  However, the restriction proposal of the EU chemicals agency ECHA includes about 10,000 PFAS substances with overall very heterogeneous properties. The proposal thus does not do justice to a targeted strategy. Among others, fluoroplastics are affected, which, according to the OECD definition, almost all fall into the category of "polymers of low concern" for human health and the environment due to their properties.  Therefore, the IGBCE advocates a revision of the current, largely blanket restriction proposal and a differentiated and risk-based assessment and regulation of the group of chemicals. The proposal must be based on the manufacturing conditions and areas of use, which must be safe and clean, and must be flanked by comprehensive education and training, so that the appropriate qualifications are guaranteed to protect workers.  The IGBCE advocates a balanced approach to PFAS substances that takes into account all three pillars of just transition - social, environmental and economic. |

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| 9583 | Date:  2023/09/25 23:50  Content:  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  National NGO  Org. name:  Fidra  Org. country:  United Kingdom | General Comments:  Fidra welcomes the opportunity to comment on the restriction proposal prepared by the authorities from Denmark, Germany, the Netherlands, Norway and Sweden, on per- and poly-fluoroalkyl substances (PFAS).  Nine processes have been identified that are critical to the resilience and stability of the whole Earth, and are strongly affected by human actions. These have been named the ‘planetary boundaries’, and a recent update of the planetary boundaries framework indicates that six of the nine have been passed, placing the Earth outside the safe operating limit for humans (Richardson et al, 2023) . One of the six planetary boundaries is ‘novel entities’ which are novel anthropogenic inputs to the Earth’s system, including synthetic chemicals such as endocrine disruptors and organic pollutants. While this category would be assumed to include PFAS, it has been suggested that contamination of the environment by this group of chemicals actually ‘defines a separate planetary boundary’ which has in turn been exceeded (Cousins et al, 2022) . The current capacity to address the removal of PFAS and mitigate their impact once in the environment is very poor, and it is therefore highly important to restrict uses and emissions of PFAS as soon and as comprehensively as possible.  Fidra strongly supports the overall aim of the proposal submitters, to restrict PFAS as a group, as also outlined in the EU Chemicals Strategy for Sustainability published in October 2020 (European Commisson, 2020) . PFAS have been described by researchers as probably the greatest chemical threat the human race is facing in the 21st century, and there needs to be movement now beyond addressing them one by one.  We are constantly learning more about the levels of PFAS in the environment and their impacts, and none of it is reassuring. A recently published study of 12 killer whales found that PFAS made up more than half of the contaminants in them (Lee et al, 2022) . Not only do the results found by this investigation show we need to improve monitoring, we also need to urgently address the discharge of all PFAS into the environment and take action to prevent it. The widespread contamination of the environment by PFAS (Arena for Journalism in Europe, 2023) and the presence of PFAS in our bodies (Uhl et al, 2023) are further indicators that urgent action is needed.  These concerns are addressed well by the restriction proposal that is under consideration here. Restricting the manufacture, use and placement on the market of PFAS, with significant reductions by the end of the transition periods, will be vital steps towards a truly PFAS-free economy in the EU. It is essential that the broad scope of the restriction continues to cover all very persistent PFAS and includes fluoropolymers, and minimal derogations are included. Transition should be ensured for all uses where alternatives are available, in as short a time as possible. Importantly, the use of PFAS as active ingredients in Plant Protection Products, Biocidal Products and Human and Veterinary Products should not be given a derogation for an unlimited timescale.  The potential economic impact of moving away from PFAS production is often cited as a reason for their ongoing use, however, continuing on the current trajectory of PFAS use will inevitably have its own economic impact (ChemSec, 2023) . PFAS are building up in the environment, ultimately threatening food and drinking water security and public health. As more evidence comes to light about the human impacts of these chemicals, the tolerable limits are repeatedly decreased, therefore, we are tending to a point where the levels in food overtake safe levels. Farms and fisheries may be left with products that are unable to be sold because of unsafe levels of PFAS and drinking water will need a higher degree of treatment to make it safe. As a real-world example of this, the state of Maine has retrospectively fitted filters to individual houses to make drinking water safe, with its estimated costs of PFAS drinking water remediation over 2022-2030 of $42.5 million (The Maine Monitor, 2023) . Furthermore, the impacts to human health from long term repeated exposure to PFAS, will inevitably put further strain and economic pressure on healthcare providers. The health-related costs of inaction has been estimated at 52 – 84 billion EUR for the European Economic Area (Nordic Council of Ministers, 2019) .  Justification for a full group approach Piecemeal regulatory approaches to PFAS management implemented so far have been inadequate in preventing their release into the environment. In addition, ‘chemical-by-chemical’ approaches have led to the substitution of regulated PFAS with other, similarly problematic, unregulated PFAS. They have created a never-ending cycle of regrettable substitution that has undermined genuine progress towards safe and sustainable alternatives. Regulating all PFAS as one group is the only way to end this never-ending cycle of regrettable substitutions and to cover persistent PFAS which may not even be engineered yet. It is also the most efficient way to address the urgency of reducing PFAS emissions. In an ideal scenario, a restriction takes 3 years from the registry of intention until entry into force. A multiplication of regulations for different subgroups would significantly delay action on highly persistent PFAS.  The fluoropolymers subgroup of polymeric PFAS have been singled out by some commentators as being of ‘low reactivity’ and therefore not in need of restriction. However, independent peer-reviewed scientific literature stresses that their production, use and end of life, are associated with emissions of other PFAS posing an unacceptable risk to human health and the environment (Lohmann et al, 2020; Kwiatkowski et al, 2020) . In addition, as extremely persistent materials, fluoropolymers represent a long-term reservoir for the emissions of associated PFAS in the environment. Therefore fluoropolymers and other polymeric PFAS must be in the scope of regulatory actions on PFAS to achieve the aim of reducing emissions of highly persistent PFAS to a minimum.  It is vital that all sectors which use PFAS come within the scope of a single set of overarching regulations, as regulations applicable to individual sectors such as food contact materials, plant protection products, pharmaceuticals and F gas will not consider the full spectrum of environmental and human health impacts of a PFAS product’s entire life cycle. Rather the sector-specific regulations will address the safety and toxicity around a product’s function. Where this is a consumer product, such as food contact materials, the focus is on human health while using the product, rather than the environmental impact of its production, disposal and end of life. An overarching regulatory approach to restrict the use of PFAS as a group will address such loopholes.  With increasing evidence of PFAS in our environment, there is an urgent need for commitments to stopping PFAS emissions at source by moving towards a PFAS-free economy.  Increasing evidence of PFAS exposure and accumulation Whilst we wait for visible action to restrict PFAS, the evidence of the harmful effects of PFAS and their accumulation in the environment and human and wildlife populations continues to build (European Environment Agency, 2019) . PFAS continue to be a serious chemical global threat through their negative health effects in humans and wildlife (Agency for Toxic Substances and Disease Registry, 2022) . The actual risk of PFAS is high, but many people remain unaware of them (Wickham & Shriver, 2021) . Recently published research shows that in 2019, at least one PFAS was detected in 60% of the public groundwater wells and 20% of the private groundwater wells used as drinking water sources in the eastern USA (McMahon et al, 2022) . In England, the Environment Agency found PFAS contamination in 97% of 470 freshwater sites analysed between 2014 and 2019 (Environment Agency, 2021) . The latest reports from the UK’s Water Industry Research (UKWIR) Chemicals Investigation Programme show that effluent from monitored wastewater treatment works is exceeding the Environmental Quality Standard (EQS) of PFOS. In the case of monitoring effluent released in transitional and coastal waters PFOS has been found to be more than 10 times the EQS across all sites monitored. Analysis by The Rivers Trust and Wildlife and Countryside Link has shown PFAS to be widespread in English rivers with 81 of 105 sites surveyed containing PFAS at levels which would not meet tougher new proposed EU standards.  Researchers have also found freshwater contaminants accumulate in plants and animals, where they can be transferred to humans via ingestion (Roth et al, 2020) . A US study published in January 2023 found freshwater fish with widespread high levels of PFAS, which if eaten would be equivalent to drinking contaminated drinking water (Barbo et al, 2023) . Distributed by the water cycle, PFAS have been allowed to contaminate remote corners of the planet and negatively impact its wildlife. In Antarctica, accumulations of the PFAS perfluorobutanoic acid in snow increased more than 200-fold between 1957 and 2015 (Garnett et al, 2022) .  Researchers have also found high concentrations of PFAS in Arctic algae (Garnett et al, 2021) . Algae are an important food source for zooplankton, with their contamination feeding upwards through the food chain to fish and shrimp, then seals, and finally to apex predators such as polar bears. For many people, current PFAS exposure levels are unlikely to be high enough to warrant serious concern. However there is increasing evidence that they affect early brain development (Eriksson et al, 2023) . For adults, exposure in some occupations, including firefighting and chemical manufacturing and processing, are likely to be much higher than others (United States Environmental Protection Agency, 2023) . Links between serious health conditions and occupational exposure are increasingly emerging (Shearer et al, 2020; Purdue et al, 2023) and will continue to do so as worldwide research, knowledge and understanding of PFAS increases, and as long as PFAS are not restricted or replaced.  Development of PFAS-free alternatives is crucial and already underway The achievement of a PFAS free economy will impact manufacturers of PFAS and to a lesser extent others who import, supply, formulate or distribute mixtures and articles that contain PFAS in the EU. It is therefore vital that the transition to a PFAS-free economy is undertaken in a way that protects jobs and communities as well as the environment, especially for manufacturers of PFAS and small or medium businesses specialised in PFAS-based technologies. There is no one size fits all approach and context-specific solutions to support a job transition will need to be drawn up that centres workers and impacted communities in decision making.  The transition away from PFAS has the potential to bring real economic benefit. As a group of highly persistent, toxic chemicals, the continued use of PFAS is at odds with meeting the sustainability needs of modern businesses and the shift to a circular economy. Regulatory incentives to promote PFAS substitution and identify safer chemical and non-chemical alternatives will drive innovation towards new and emerging markets.  Transition will vary in pace according to the availability and scale of alternatives. Therefore the opportunity for rapid transitions where existing alternatives exist should not be delayed by consideration of substitutions that are not yet possible. The common characteristics of rapid transitions, include where a new and well established technology simply substitutes for an old one, where substitute technologies have been previously used in other markets, benefitting from the experience of early adopters, where the scales, either national or sub-national, are relatively small, and finally where the technologies offer high tangible benefits for adopters such as health, as well as benefiting from well-designed public policies (Grubler, Wilson & Nemet, 2016) .  To achieve a PFAS-free economy it will be essential to have a regulatory framework with policies to restrict PFAS use, to drive demand for PFAS-free products, as well as policies to support a transition with minimal impact on workers and communities affected by the move to a PFAS-free economy, especially those employed by or closely connected to manufacturers of PFAS and small to medium businesses specialised in PFAS-based technologies.  An essential step of the transition away from PFAS is the creation of a substitution hub. It would centralise information regarding PFAS-free alternatives for various sectors and applications, provide expertise and introduce PFAS users to alternative providers (see for instance ChemSec Marketplace as a model (ChemSec, 2023) ). In addition, governments need to play a pivotal role in supporting the research and innovation needed to develop and adopt PFAS-free alternatives. The substitution hub could also coordinate actions around R&D needs by identifying the gaps in PFAS-free alternatives and facilitating the introduction of companies with scientists to develop alternatives (See for instance the model of the Toxics Use Reduction Institute (TURI) at the University of Massachusetts Lowell (UMass Lowell), with the success story of PFAS-free alternatives developed for semiconductor uses in a year (UMASS LOWELL, 2023) ).  Conclusion Society must end its reliance on PFAS and the encouraging news is that the transition to a PFAS-free economy is already underway. Progressive companies are switching to PFAS-free products, technologies or alternatives, such as the outdoor wear producer Patagonia (Patagonia, 2023) . PFAS-free alternatives have been developed in the past decades for critical applications such as firefighting foams and new PFAS-free alternatives are being found for sectors considered challenging until recently, such as the semiconductor (Sharma et al, 2023) and hydrogen production sectors (Fraunhofer IAP, 2023) . Regulation is the strongest incentive to push for substitution (Tuncak, 2013) and the restriction is the best way to ensure a full phase out of all PFAS manufacturing, uses and placement on the market. In addition, a restriction allows the inclusion of derogations for specific uses in need of longer transition periods, allowing some flexibility. Finally by covering imports, a restriction allows a level playing field for all companies.  References: Richardson, K. et al (2023) Earth beyond six of nine planetary boundaries. Science Advances, 9, eadh2458. Cousins, I.T. et al (2022) Outside the safe operating space of a new planetary boundary for per- and polyfluoroalkyl substances (PFAS). Environmental Science & Technology, 56, 11172-11179. European Commission (2020) Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. 25pp. Brussels, 14.10.2020 COM(2020) 667 final. Available at https://echa.europa.eu/hot-topics/chemicals-strategy-for-sustainability. Lee. K. et al (2022) Emerging Contaminants and New POPs (PFAS and HBCDD) in Endangered Southern Resident and Bigg’s (Transient) Killer Whales (Orcinus orca): In Utero Maternal Transfer and Pollution Management Implications. Environmental Science & Technology, 57, 360-374. 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| 9584 | Date:  2023/09/25 23:48  Content:  Hazard or exposure  Description of analytical methods  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  We are a manufacturer of medical in-vitro diagnostic products (PCR Kits) for infectious deasease diagnostics of pathogenic viruses and bacteria. This covers our direct role as a provider of in-vitro diagnostic PCR kits to facilitate diagnostics and therapy. But also as part of the society and individual citizens we care for the environment and are concerned about chemicals accumulating in nature and humans. As medical in-vitro diagnostics PCR kit manufacturer we are part of an industry with long and complex supply chains. From what we know it is very likely that among the many instruments and parts we purchase from our direct suppliers there are parts that either contain PFAS or where PFAS are involved during the manufacturing process.  During the consultation period it was not possible for us to perform a complete and thorough analysis, which of our instrument parts and in-vitro diagnostic PCR kit components would be affected by a potential ban of PFAS. We as a small and medium enterprise, order very low volumes of materials compared to consumer product companies or the automotive industry, but nevertheless require high quality products and many proofs for regulatory purposes. This results in a very low impact and priority with our suppliers. As a manufacturer we do not purchase PFAS directly. As the knowledge which diagnostic instrument parts and PCR Kit components possibly involving PFAS often is not available at our direct supplier but is only available further upstream in the supply chain, gathering information is a time consuming and sometimes futile endeavor. This absence of support is hard to show as supporting evidence.  Publicly available information show that metal parts, certain polymer parts or electronics containing PTFE, PVDF, PFA or PFPE or using these polymers during manufacturing would be subject to the ban. This will result in major efforts to replace these materials, while even the major chemical companies do not provide or promise replacement materials in the foreseeable future. Even when those would be available at some point in the future the effort to introduce the replacement within engineering is calculated by us to be 2 to 3 years with minimum further 3 years to validate their application in medical in-vitro diagnostics products. The necessary change control and gathering of clinical data is strongly enforced by the notified bodies following EU regulation. As there are presently no replacement materials available the cost of engineering and validation cannot be calculated to be presented as supporting evidence.  It is very likely that following a PFAS ban as planned many of the medical in-vitro diagnostics products listed below under “1 Sectors and (sub-)uses” will be discontinued and be no longer available for patients benefit. Even with the maximum derogation time a timely replacement of PFAS and uninterrupted availability is far from sure. For us as an SME medical in-vitro diagnostics PCR kit manufacturer it is impossible to give detailed substantiated information on the alternatives and efforts needed after a complete ban of PFAS. However, the very likely consequence will be a discontinuation of medical in-vitro diagnostics PCR kit for PCR diagnostics of e.g. new variants of SARS CoV19 and many other pathogenis viruses that are in daily use all over Europe! |
| Answer to specific info request 1:  Sector: Medical in-vitro diagnostic PCR Kits. We request that "In-vitro diagnostic PCR Kits / ca. 10.000 Kits (100 PCR tests each) in 2019-2021" be newly added to derogation as missing uses. |
| Answer to specific info request 6:  As already stated in the general comments, the medical in-vitro diagnostic PCR Kits listed under 1. Sectors and (sub-)uses are very likely affected by a PFAS ban, as their development, production and application requires plastic consumables and PCR instruments consist of parts and materials listed in many other sectors covered in the Restriction Report e.g. electronics or coated metal parts. Missing these products will very likely lead to a discontinuation of the listed medical in-vitro diagnostic PCR Kits and instruments after a PFAS ban. Even when replacement materials for these PCR Kits and instruments would be available at some point during a derogation period, we as a medical in-vitro diagnostic PCR Kit manufacturer would have only the remaining time of said derogation period to engineer and validate the use within our medical in-vitro diagnostic PCR Kits. The current enforcement of the medical in-vitro diagnostic PCR Kit and instrument regulation is very clear regarding the necessary proofs. We therefore request the exemption or at least the maximum derogation period of 12 years for the products listed under 1. Sectors and (sub-)uses on the basis of the negative impact on patient care if said medical in-vitro diagnostic PCR Kits and instruments would be no longer available due to the non- availability of necessary pre-products and the time-consuming revalidation after technical changes. |

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| 9585 | Date:  2023/09/25 23:50  Content:  Hazard or exposure  Environmental emissions  Baseline  Other socio economic analysis (SEA) issues  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Profiroll Technologies GmbH  Org. country:  Germany  Attachment: | General Comments:  Würdigung von Werkzeugmaschinen im Annex XV Restriction Report  Gewinde- und Profilwalzmaschinen werden weltweit eingesetzt, um durch Massiv-Kaltumformung rotationssymmetrische, metallische Werkstücke, wie Schrauben, Verstärkungs- und Befestigungselemente, Getriebewellen, Achszapfen, Antriebswellen, Verfahr- und Verstellspindeln, Bohrer und Getriebeschnecken herzustellen. Die extreme Effizienz des Verfahrens sowohl in Hinblick auf sehr kurze Taktzeiten, sehr geringen Energieverbrauch und 100-prozentige Materialausnutzung (keine Späne, Abfall oder Verschnitt) führte zur Verdrängung der spanenden Fertigung in vielen Bereichen. Gewinde- und Profilwalzmaschinen stellen heute somit eine entscheidende Grundlage für die Herstellung von Komponenten der Automobilbranche, für Haushaltsgeräte, der Elektrobranche, der Möbelindustrie, der Baubranche und der Energiebranche, insbesondere der Windenergie, dar. Verfahrensbedingt werden die Komponenten in millionenfacher Stückzahl pro Jahr hergestellt. Die Auswirkungen auf die Herstellung, den Betrieb und die Wartung von Gewinde- und Profilwalzmaschinen, auf Umformmaschinen und auf Werkzeugmaschinen zur Herstellung von Metallerzeugnissen insgesamt wird im Annex XV Report zum PFAS-Beschränkungsvorschlag absolut unzureichend untersucht und bewertet. Dabei handelt es sich um die Produktionsgrundlage eines Großteils der europäischen Industrieproduktion. Unter Punkt 1.3.2.4 finden sich nur zwei Sätze, die grobe Schätzungen zum Ausdruck bringen und lediglich Bezug auf den Teilbereich "Metallbeschichtung" nehmen. Dennoch wird in Tabelle A.1 des Annex A die Anwendung "Metallbeschichtung + Herstellung von Metallerzeugnissen" als "im Detail untersucht" ausgewiesen. In Tabelle 8 und 9 des Anhang XV des Beschränkungsberichts wurden die ´Folgen gar nicht explizit bewertet und lediglich auf andere Sektoren (Transport und Bau) verwiesen. In diesen wird nur auf sehr kleine Teilaspekte der "Herstellung von Metallerzeugnissen" eingegangen.   Auswirkungen der Beschränkungen  Nachfolgend sollen daher einige Auswirkungen der vorgeschlagenen PFAS Regulierung am Beispiel der Gewinde- und Profilwalzmaschinen aufgezeigt werden:  1. Radialwellendichtringe aus FKM und/oder mit PTFE-Beschichtung Kommen in den meisten Getrieben und weiteren schnell drehenden Lagerstellen zum Einsatz. Hohe Drehzahlen insbesondere an der Eingangswelle der Getriebe lassen den Einsatz von herkömmlichen NBR-Werkstoffen nicht zu, da diese für die entstehenden hohen Temperaturen nicht geeignet sind. (siehe Anhang "Radialwellendichtring-Umfangsgeschwindigkeit") In der Vergangenheit wurden NBR-Dichtungen gezielt durch FKM-Dichtungen ersetzt, da beim Einsatz von NBR-Dichtungen bereits nach kurzer Nutzungsdauer Leckagen auftraten, die bis zur Zerstörung der Getriebe führen konnten. Auf Nachfrage konnten durch die Dichtungshersteller keine vergleichbar leistungsfähigen Alternativen für die Umgebungsbedingungen hohe Drehzahl, hohe Umlaufgeschwindigkeiten, Temperaturen größer 80°C, synthetische und mineralische Öle, KSS-Emulsion bereitstellen. Folgen: - deutlich verkürzte Austauschintervalle - notfalls Reduzierung der möglichen Drehzahlen mit entsprechenden Produktivitätseinbußen - erhöhte Reibung und somit erhöhter Energieverbrauch - Erhöhung der Risiken durch Austritt wassergefährdender Stoffe  2. Dichtelemente in Hydraulikzylindern zur Vorschuberzeugung Kommen in Walzmaschinen zur Erzeugung der Vorschubbewegung zum Einsatz. Einsatz der Alternativen aus UHMW-PE und TPU wegen Temperatur Bereich größer 80°C und hohen Drücken bis ca. 250 bar kritisch. Folgen: - deutlich verkürzte Austauschintervalle - erhöhte Reibung und somit erhöhter Energieverbrauch - keine Ersatzteilversorgung für tausende im Markt befindliche Maschinen (Sonderbauformen) 3. metallische Gleitbuchsen Kommen in den teils extrem beengten Bauräumen im Arbeitsraum der Maschinen zum Einsatz. Platzverhältnisse lassen keine Wälzlager und Rollenführungen zu. Kunststoffe und metallische Werkstoffe ohne PFAS zeigen einen deutlich höheren Verschleiß und zu geringen Widerstand gegen die eingesetzten Kühlsschmierstoffe. "Bronze-Buchsen" wurden in der Vergangenheit aufgrund von gehäuften Ausfällen gegen Gleitbuchsen mit PFAS-Beschichtungen eingesetzt. Folgen: - deutlich verkürzte Austauschintervalle - sehr hoher Austauschaufwand, da die Komponenten tief in der Maschine verbaut sind - hohe Maschinenstillstandzeiten zur Wartung  Weitere Problemfelder sind die Dichtungen von Pneumatikzylindern, Linearführungen und lebensdauersteigernde Beschichtungen von Hochleistungswälzlagern.  Für alle beschriebenen Anwendungsfälle ist weiterhin festzustellen, dass diese fest in ortsfesten Maschinen verbaut sind und bei bestimmungsgemäßer Verwendung nicht in die Umwelt gelangen. Voraussetzung ist eine fachgerechte Entsorgung durch Verbrennung, welche gemäß Anhang XV des Beschränkungsberichts möglich ist.  In Tabelle 4 des Anhang XV des Beschränkungsberichts werden dem Sektor ein mittlerer Tonnagebereich (3), geringe Emission in der Herstellungs- und Nutzungsphase (1) sowie ein geringer Beitrag zur Gesamtemission (1) bescheinigt. Angesichts des extrem negativen Einflusses der vorgeschlagenen PFAS-Beschränkungen auf Gewinde- und Profilwalzmaschinen im Besonderen und Werkzeugmaschinen zur Herstellung von Metallerzeugnissen insgesamt, erscheinen die vorgeschlagenen Beschränkungen unverhältnismäßig.  Eine pauschale Beschränkung gemäß des vorliegenden Vorschlags berücksichtigt nicht die konkreten Risiken. Eine Risikobewertung der einzelnen PFAS ist notwendig, ebenso der bestimmter zusammenfassbarer Anwendungsszenarien. Anwendungen und Stoffgruppen mit geringem Risiko (z.B. Dichtungen) sollten über Ausnahmegenehmigungen nutzbar bleiben. Ebenso bedarf es einer Ausnahmeregelung für Ersatzteile bereits im Markt befindlicher Maschinen. |

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| 9586 | Date:  2023/09/25 23:52  Content:  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  VDMA e.V. Arbeitsgemeinschaft Brennstoffzellen  Org. country:  Germany | General Comments:  Betroffenheit im Maschinen- und Anlagenbau: Von einer potenziellen zukünftigen PFAS-Beschränkung nach Vorlage des vorliegenden Beschränkungsdossiers sind nahezu alle Hersteller des Maschinen- und Anlagenbaus entweder in den Produkten oder in der Produktion betroffen, wenn auch in unterschiedlichem Ausmaß. Eine sehr große Betroffenheit gibt es beispielsweise bei den Herstellern von Hydraulikkomponenten wie Pumpen, Motoren, Ventile und Zylinder, sowie Armaturen und Kompressoren. Die Liste erhebt keinen Anspruch auf Vollständigkeit. Häufig werden PFAS, größtenteils fluorierte Polymere, beispielsweise in Dichtungen, Schläuchen, Leitungen, Ventilen, und Beschichtungen eingesetzt. Während sich in einigen Fällen „nur“ die Performance vieler Produkte massiv verschlechtern würde, könnten viele Produkte gar nicht mehr hergestellt, importiert und in Verkehr gebracht werden, so dass vielen Unternehmen durch ein PFAS-Verbot die Geschäftsgrundlage vollständig oder teilweise entzogen würde.   Gefährdung der Klimaziele Ein pauschales PFAS-Verbot, wie es aktuell im Rahmen der REACH Verordnung vorgeschlagen wird, gefährdet die Klimaziele. Ohne PFAS-Materialen lassen sich die Schlüsseltechnologien der Transformation zur Klimaneutralität nicht produzieren. Damit können auch die Ziele der Energie- und Mobilitätswende nicht erreicht werden. Kein Windrad, kein Energiespeicher, kein E-Auto, keine Halbleiter. Ohne per- und polyfluorierte Alkylsubstanzen (PFAS) lassen sich die Schlüsseltechnologien der Transformation zur Klimaneutralität nicht produzieren und damit die Energie- und Mobilitätswende nicht umsetzen. Die Stoffe werden umfassend in Querschnittstechnologien, beispielsweise als Dichtungen und Kabel, verbaut und in allen relevanten Schlüsseltechnologien eingesetzt, die maßgeblich über den Erfolg des Green Deal mitentscheiden werden. Auch Lithium-Ionen-Batterien oder Wasserstofftechnologien sind dringend auf PFAS angewiesen. Neben einer zu Diskussion stehenden 5 Jahre Ausnahmeregelung für PEM Brennstoffzellenmembranen werden aktuell keine weiteren Ausnahmen von diesem Verbot für Wasserstofftechnologien für den energie- und Verkehrssektor vorgeschlagen. Somit ist mit einem solchen PFAS-Verbot die Erreichung der Ziele der Klimaneutralität in der EU im Jahr 2050 und die dafür erforderlichen Zwischenschritte auf dem Weg dorthin nicht zu erreichen. Auswirkungen auf Brennstoffzellen und Elektrolyseuren Ein mögliches Verbot der PFAS-Stoffe betrifft die Brennstoffzelle und den Elektrolyseur entlang der Produktions- und Wertschöpfungskette. Angefangen bei der Produktion dieser Technologien: Produktion der Brennstoffzelle bzw. dem Elektrolyseur (Anlagenbau); Produktionshilfsmittel (z. B. Schmiermittel und Hilfsmaterialien); Systemkomponenten (Ventile, Schläuche und andere) und Balance-of-Plant Komponenten (wie Pumpen, Filter) bis hin zu den funktionellen Komponenten des Stacks. PFAS-Polymere sind elementar für die Brennstoffzelle und den Elektrolyseur und werden hier aufgrund ihrer Eigenschaften (Leitfähigkeit, Wasser-Stabilität, Abfuhr von Reaktionswärme, chemische Stabilität) gezielt eingesetzt, um die Funktionalität und Lebensdauer zu erreichen. Folgende Schlüsselkomponenten im Brennstoffzellen- und Elektrolyseur-Stack sind ohne aktuelle PFAS-freie Alternativen: - Elektrodenmembran - Gasdiffusionsschicht (GDL) - Anoden- und Katalysatorschicht - Porösetransportschichten (Elektrolyseur)  In den letzten 20 Jahre wurden keine PFAS-freien Materialien zum Einsatz in den beiden genannten Technologien identifiziert, die auf ein kommerzielles Niveau oder einen Produktionsmaßstab übertragen werden können. Mit alternativen Materialen und eine für den Markt notwendige industriellen Realisierbarkeit ist erst – wenn überhaupt - nach etwa 25 Jahren zu rechnen.  Forderungen Die VDMA Arbeitsgemeinschaft Brennstoffzellen (VDMA AG BZ) vertritt mehr als 90 Mitglieder entlang der Wertschöpfungskette der Brennstoffzellen- bzw. Wasserstoff-Technologie; Herstellern von Produktions- und Prüftechnik, Hersteller von Stack-Komponenten, System-Komponenten und Systemen sowie Forschungsinstituten. Bei einer Befragung unter den Mitgliedern der VDMA AG BZ gaben 30 % der teilnehmenden Unternehmen an, bei einem PFAS-Verbot, wie es aktuell zu Diskussion steht, keine weiteren Investitionen in Europa mehr getätigt werden würden.  Die grundsätzliche Bestrebung zur umweltbewussten Verwendung von PFAS zum Schutz von Menschen und Umwelt ist zu begrüßen. Jedoch fordern wir - eine differenzierte Betrachtung und Regulierung entlang der Wertschöpfungskette und in Abwägung der Erreichung der Klimaziele. - längere Übergangsfristen. - Gleichbehandlung von Elektrolyseuren und Brennstoffzellen. - Unbürokratische Beantragung der Verlängerung von Ausnahmen  Brennstoffzellen und Elektrolyseure ohne PFSA-Materialien sind derzeit und auf absehbare Zeit nicht realisierbar. Wir betrachten eine Ausnahme für die Brennstoffzellen- und Elektrolyseuren-Technologie als notwendig. |
| Answer to specific info request 1:  Energy sector (Annex E.2.12.) |

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| 9587 | Date:  2023/09/25 23:51  Type:  BehalfOfAnOrganisation  Org. type:  National Authority  Org. name:  United States Department of State/ United States Government  Org. country:  United States of America | General Comments:  The United States believes that per- and polyfluoroalkyl substances (PFAS) are an urgent public health and environmental issue and appreciates that the European Union and the other members of the European Economic Area (EEA) also recognize the need to address the risks to human health and the environment posed by PFAS. We agree that the widespread use and potential harmful impacts of PFAS on the environment and human health require significant actions. We appreciate the EU’s attention to addressing the ongoing and emerging challenges stemming from the widespread use of PFAS in consumer and commercial products, including cleaning agents, food packaging, and textiles, and we appreciate this opportunity for the public to offer comment on the proposal. However, we also recognize that there is not yet a consensus on how to regulate these substances.  We also recognize that members of the international community, including the United States, are taking differing approaches to addressing PFAS. The Biden-Harris Administration is committed to ensuring all communities, and particularly those overburdened with exposures and with environmental justice concerns (1), have access to clean air, water and food free from the harmful effects of PFAS contamination (2). Domestically, nearly two dozen U.S. agencies and offices are involved in addressing risks posted by PFAS-related activities, with cross-agency coordination through the White House Council on Environmental Quality and Office of Science and Technology Policy. The U.S. Environmental Protection Agency (EPA) has released and is implementing the PFAS Strategic Roadmap to support research, restriction, and remediation of PFAS throughout the United States (3). The United States is of the view that we need increased and sustained leadership across all levels of government for the protection of affected communities and workers, remediation of PFAS contamination, prevention of new PFAS exposures and contamination, and production of innovative breakthroughs in the scientific understanding of PFAS chemistry and persistence, effective and safe alternatives, broader investigation of known and potential PFAS health effects, and alternatives to PFAS. To support these efforts, federal organizations are currently gathering information to better evaluate a wider range of newer and less understood PFAS, including their environmental and human health impacts. Much of this work is being conducted on individual substances or on groups or categories of PFAS; the United States recognizes that its approaches are likely to evolve to allow for more expedited and efficacious analyses as more scientific information becomes available.  The United States notes that the proposal before ECHA is broad in its approach toward restricting PFAS in commerce. While the proposal to ban the production of certain PFAS or certain uses of PFAS may ultimately be necessary to protect against human health and environmental risks, the United States believes that robust regulation and remediation of PFAS through other mechanisms is also necessary to ensure the safe use of those substances already in commerce, particularly for uses critical to the functioning of society. Furthermore, the United States believes that regulatory efforts should be paired with continued research and data gathering to enhance the body of knowledge on the human health effects and environmental impacts of PFAS, which, in turn, will improve the scientific foundation for effective risk management across the spectrum of PFAS as well as the development of safe and sustainable alternatives.  We expect that restrictions on PFAS will have a broad trade impact across sectors and industry continues to express the need for time to arrive at alternative solutions. The United States looks forward to continuing to discuss with the EU approaches to both reduce ongoing and future PFAS exposures throughout its lifecycle and to remediate and mitigate environmental release of PFAS. In addition, the United States supports the European Union’s legitimate objective of protecting health and the environment at the levels it considers appropriate, consistent with its international obligations. The current available scientific and technical information regarding PFAS is evolving; therefore, the United States encourages ECHA to consider any updates to scientific and technical information that become available during ECHA’s consultation with EU Member States, as well as the use of international standards where they exist or where their completion is imminent. The United States asks ECHA to develop a measure that does not create unnecessary obstacles to international trade.  The United States also urges ECHA to thoughtfully consider input provided by all stakeholders on the effects of PFAS pollution and information provided on PFAS uses and alternatives during the consultation period. We agree with concerns raised so far during the consultation process about the current lack of technically and economically feasible alternatives for potential critical or essential uses, including those for national security, critical infrastructure, and those for use in certain applications for semiconductors, medical products and devices, and batteries. We welcome an ongoing conversation on how to address such concerns.  We also want to highlight that under the proposal, PFAS constitutes a group of thousands of man-made chemicals, including nearly all hydrofluorocarbons (HFCs) controlled under the provisions of the Kigali Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer, as well as many of the climate-friendly alternatives to these substances. Therefore, there is already global agreement to phase down the production and consumption of the HFCs in a stepwise fashion. If these HFCs and HFC substitutes are prematurely no longer allowed to be used, this could negatively impact the successful implementation of the Montreal Protocol’s global phasedown, putting at risk significant climate benefits of avoiding up to half a degree Celsius of warming (4). Additionally, it is important to maintain the Montreal Protocol’s phaseout of ozone-depleting halons, which are commonly used in fire suppression. There are the few potentially viable alternatives to halons for certain crucial fire suppression applications. Therefore, we urge the EU to consider the global effort to fully implement the Montreal Protocol when considering the need to include flexible restrictions or derogations within the REACH authorizing laws and policies.  Finally, we would like to make note of several inaccuracies presented in Section 2.2.1.5, which makes mention of PFAS-related legislation outside of the EU.  • First, the description of U.S. legislation begins with a discussion of the PFAS Action Act, which is legislation introduced in the U.S. House of Representatives in 2019 and 2021 but did not become law, nor has it been reintroduced in the current (118th) U.S. Congress. It therefore does not represent operable U.S. legal authority with respect to PFAS and we recommend it be deleted within this description of enacted U.S. legislation. The United States is happy to provide updates on enacted U.S. legislation to the extent such updates are useful as the restriction proposal is further considered.  • Second, the description includes mention of the 2019 National Defense Authorization Act, but neglects to mention other key PFAS-related provisions of U.S. law, including significant provisions in the Fiscal Year 2020 National Defense Authorization Act. Reliable syntheses of PFAS-related legal authorities in the United States exist from sources such as the U.S. Congressional Research Service (e.g., Federal Role in Responding to Potential Risks of PFAS (5)).  • Third, the summary includes a map generated by the Environmental Working Group, a non-governmental organization in the United States. For a U.S. government resource, we would recommend instead citing the EPA’s PFAS Analytic Tools (6), released in January 2023. U.S. EPA’s tools contain location-specific information related to PFAS manufacture, release, and occurrence in the environment as well as facilities potentially handling PFAS.  The United States looks forward to continued discussions with the EU, both bilaterally and in appropriate multilateral fora, with respect to the challenges in protecting human health and the environment from the risks posed by PFAS while preventing significant disruptions in the production and use of materials that may be considered critical or essential.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (1) Federal Register, Revitalizing Our Nation's Commitment to Environmental Justice for All: https://www.federalregister.gov/documents/2023/04/26/2023-08955/revitalizing-our-nations-commitment-to-environmental-justice-for-all  (2) Biden-⁠Harris Plan to Combat PFAS Pollution: https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/18/fact-sheet-biden-harris-administration-launches-plan-to-combat-pfas-pollution/  (3) U.S. EPA PFAS Strategic Roadmap: https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap\_final-508.pdf  (4) World Meteorological Organization (WMO), Executive Summary. Scientific Assessment of Ozone Depletion: 2022, GAW Report No. 278, 56 pp., WMO, Geneva, Switzerland, 2022.  (5) U.S. EPA PFAS Analytic Tools: https://crsreports.congress.gov/product/pdf/R/R45986  (6) U.S. Federal Role in Responding to Potential Risks of PFAS: https://echo.epa.gov/trends/pfas-tools |

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| 9588 | Date:  2023/09/25 23:50  Content:  Scope or restriction option analysis  Information on alternatives  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  The Association of Lithuanian Chemical Industry Enterprises  Org. country:  Lithuania | General Comments:  As a member of the European Chemical Council (Cefic), the Association of Lithuanian Chemical Industry Enterprises adheres to the position of the sectoral group FPP4EU and at the same time wants to pay attention to the aspects of the proposal. Substances classified as PFAS are not produced in Lithuania, so the position reflects the position of downstreamusers. From the conducted surveys, it can be concluded that PFAS chemicals, mainly (PTFE: polytetrafluoroethylene) CAS No. 9002-84-0 are used in the country in high-temperature processes or when working in an aggressive environment in large-scale production. Also in high-tech areas, e.g. production of lasers, medical devices. Such consumption could be identified based on the purchases of plastics, but there are a number of areas, devices, installations that can be assumed, but exact data are not available. The proposal contains detailed material on PFAS in various professional and consumer products. However, this list may not be complete, e.g. fluorocarbon fishing line.  We believe that the self-imposed restriction of 10,000 chemicals, regardless of the risks involved, is unjustified. The listed chemical substances differ in their properties, utilization possibilities and other parameters.  The industry already complies with the strictest chemical regulation and the restriction should not limit industrial production activities, burdensome control procedures should not be created.  Recognizing the sense of the restriction, we believe that the competitiveness of the European industry should be taken into account, accordingly ensuring the control of the entry of PFAS into the EU economic space, assessing the entire production chain. |

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| 9589 | Date:  2023/09/25 23:52  Content:  Scope or restriction option analysis  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  medac Gesellschaft für klinische Spezialpräparate mbH  Org. country:  Germany  Attachment: | General Comments:  1. The German pharmaceutical company medac Gesellschaft für klinische Spezialpräparate mbH from Wedel and Tornesch (Germany), with its subsidiaries Oncotec Pharma Produktion Gmbh in Dessau-Roßlau (Germany) and Oncomed Manufacturing a.s. in Brno (Czech Republic), which specialise in the production of medicinal products, is a producer and supplier of essential and supply-critical medicinal products to combat cancer and autoimmune diseases. As a member of the German Pharmaceutical Industry Association (BPI) and the German Chemical Industry Association (VCI), we have participated in the respective statements of the associations and fully endorse the positions and examples mentioned therein. Furthermore, the medac group of companies would like to take an independent position on the PFAS restriction proposal from the perspective of our production facilities and processes as well as our medicinal product portfolio as follows. 2. Polymeric PFAS are often used in our pharmaceutical production facilities due to their properties (high resistance to mechanical stress, temperature and aggressive substances such as acids and alkalis, very low chemical reactivity). The currently indispensable advantage is that under the given conditions they do not react with potential reaction partners or only react to a negligible extent. This makes them the ideal and non-replaceable material for seals, valves, coatings, hoses, rotor plates, lubricating oils, membranes, sterile filters, films or film distributors - i.e. wherever there is contact with the product in the production facilities or with consumables. The entire pharmaceutical industry and therefore our companies will continue to rely on the use of PFAS in production facilities for the foreseeable future. In addition to the application examples in the BPI statement, PFAS are currently used indispensably in our production facilities for: • Supply and exhaust air filtration for fermenters and bioreactors • Ventilation of autoclaves • Venting storage tanks • Ventilation of filling systems • Freeze dryer • Mobile containers and ventilation of transport containers • Filling and decanting vessels • Fermentation carafes • Cell culture chambers • CO₂ incubators • Storage containers and storage tanks Furthermore, sealing rings often contain components of the aforementioned PFAS eternal chemicals. In addition, the medac group is currently investing in a completely redesigned pharmaceutical production plant, during which the plant manufacturer assured our company that it would not be able to forego the installation of elements containing PFAS due to a lack of current alternatives. 3. Due to their inertness, polymeric PFAS, especially PTFE, are increasingly being used as a material that comes into direct contact with the drug. This not only guarantees the greatest possible safety of the drug, but also the occupational safety of medical professionals (e.g. immunotherapeutics), especially when administering highly effective drugs. medac is a relevant market player across Europe in the treatment of bladder cancer. The special service of medac is a combination approval as a ready-to-use application set that meets the requirements of occupational safety law, which enables the therapy to be used without special protection in urological practice. Unfortunately, not the medications themselves, but the currently approved instillation systems contain PFAS and would no longer be marketable if PFAS were banned. A large number of our oncological injection or infusion solutions are closed with Teflon-coated stoppers. Since the active ingredients are highly reactive, the Teflon coating protects the plastic closure from reactions with the aggressive medication. If alternative products with the current protective properties are available at all, their use would require extensive and cost-intensive changes to the drug approval in terms of content and time, including the necessary stability data. 4. In summary, it can be said that the proposed restriction increases the danger of a migration of the pharmaceutical industry to less strictly regulated regions and that, in particular, a part of the medicinal products that are essential and critical for supply will disappear from the European market without substitution. |

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| 9590 | Date:  2023/09/25 23:54  Content:  Scope or restriction option analysis  Hazard or exposure  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Belgium  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Protection of our commercial interests, including intellectual property | General Comments:  - |
| Answer to specific info request 1:  use sectors “Transport” – Sub-use Coating and finishings |

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| 9591 | Date:  2023/09/25 23:57  Content:  Hazard or exposure  Environmental emissions  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Switzerland  Company name confidential:  Yes  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Lithium Battery Recycling |
| Answer to specific info request 2:  Please refer to confidential attachment |
| Answer to specific info request 3:  Please refer to confidential attachment |
| Answer to specific info request 4:  Please refer to confidential attachment |
| Answer to specific info request 9:  Please refer to confidential attachment |
| Answer to specific info request 10:  Please refer to confidential attachment |

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| 9592 | Date:  2023/09/25 23:59  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Verband TEGEWA e.V.  Org. country:  Germany | General Comments:  Verband TEGEWA e. V. is an association representing a wide range of manufacturers of chemical substances and mixtures, such as surfactants, textile, paper and leather auxiliaries, colorants, cosmetic raw materials, antimicrobial agents, polymeric flocculants and allied products. TEGEWA represents more than 100 member companies from Germany, Switzerland and the Netherlands – including globally active chemical companies as well as a large number of medium-sized companies. TEGEWA member companies are mainly affected by this restriction proposal in the sectors textile and paper. Another relevant and important aspect for our member companies is the safe production of their chemical products which depends in many cases on fluorinated plant and component parts. TEGEWA fully supports the comment submitted by the German association Verband der chemischen Industrie e.V. Especially TEGEWA supports the proposal to exclude the manufacturing process and the use in plants and machinery to allow safe production and reduction of emissions as well as uses like high-tech applications, energy uses, medical technology, safety clothing. Furthermore, TEGEWA asks the Dossier submitters and ECHA to thoroughly consider the comments of EURATEX regarding textile uses, especially if these uses are necessary for protection and safety. In particular in cases where water, oil, and soil repellance at the same time is necessary and requested. For uses only need water repellancy and where alternatives are existing, TEGEWA supports the intention of the dossier submitters to restrict the use of PFAS. Regarding the scope of the restriction proposal, we would like to point out that the huge number of more than 10,000 substances do have very different chemical and physical properties. Therefore, they are very diverse. So, we question the approach of the dossier submitter that all of them fulfill the prerequisites for a REACH restriction, thus the proposal goes beyond the basic principles of REACH and exceeds the given legal framework. In particular, if there is no environmental exposure in specific applications and handling or it can be strongly minimised, a ban is not justified. So, we ask for a more differentiated assessment and regulatory approach that bans only uses that pose a risk is needed. A use for which no risk is identified must not be covered as a matter of principle. |
| Answer to specific info request 6:  We refer to the VCI and EURATEX contributions. |
| Answer to specific info request 7:  We refer to the VCI and EURATEX contributions. |