**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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| 9221 | Date:  2023/09/25 12:32  Type:  BehalfOfAnOrganisation  Org. type:  Academic institution  Org. name:  ETH Zürich  Org. country:  Switzerland  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Production of fluoropolymers |

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| --- | --- | --- |
| 9222 | Date:  2023/09/25 12:34  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  - |
| Answer to specific info request 1:  Electronics and semiconductors, Electronics sub-use: wires and cables |
| Answer to specific info request 8:  We sell PTFE coated cables as a distributor: Fluoropolymers (PTFE) are widely used as sheathing materials for cable jacket and wire insulation. PTFE sheathed cables are used e.g. in ships, trains, large machinery, motors, vehicles and customized high-temperature or chemical resistant applications due to their outstanding combination of properties (high temperature resistance, excellent to outstanding electrical properties and chemical resistance to name a few). PTFE guarantees a safe & long service time in critical applications under harsh environment conditions. Our customers use PTFE cables only when the application does not allow other cables and wires. If this restriction is implemented, it will cause extremely serious damage to the supply of the above named industries as PTFE can’t be replaced 1:1 by other polymers without losing performance. |

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| 9223 | Date:  2023/09/25 12:35  Type:  BehalfOfAnOrganisation  Org. type:  Academic institution  Org. name:  ETH Zürich  Org. country:  Switzerland  Attachment:  <redacted> | General Comments:  - |
| Answer to specific info request 1:  Production of fluoropolymers |

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| 9224 | Date:  2023/09/25 12:39  Content:  Scope or restriction option analysis  Hazard or exposure  Transitional period  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  European Plastics Converters (EuPC)  Org. country:  Belgium  Attachment: | General Comments:  Following our initial submission, EuPC intends to comment on specific applications. Since those are very diverse, each application will be covered in a separate submission. This brief addresses Engineering Polymer Shapes for Machining (EPSM), a sector group of European Plastics Converters (EuPC), a plastics sector group with diverse final applications. This submission is built upon a survey conducted across the members of Engineering Polymer Shapes for Machining. This sector involves 15,000 employees, 1.4 billion €/year in sales, and 58 million €/year in R&D investment.  Use of fluoroelastomers in polymer shapes Due to their unique chemical and physical properties, per- and polyfluoroalkyl substances (PFAS) have been widely used in various industrial and commercial applications. Within the machinery sector, we have registered the use of the following fluoropolymers: • PTFE (EC number: 618-337-2; CAS number: 9002-84-0); • PVDF (EC number: 607-458-6; CAS number: 24937-79-9); and • PFA (EC number: 682-550-7; CAS number: 26655-00-5).  Toxicity Fluoropolymers are very stable because of their intrinsic physicochemical properties. If lost in the environment, they are therefore currently considered as persistent. However, they do not display any hazardous property/property of concern referred to by the dossier submitter; i.e., bioaccumulation, mobility, long-range transport potential (LRTP), accumulation in plants, ecotoxicity, endocrine activity/endocrine disruption, effects on human health and concerns triggered by a combination of these properties. Moreover, PTFE and PFA, as fluoropolymers, meet the OECD criteria for polymers of low concern [1,2]. Regarding residual monomers in articles made from fluoropolymers, it is theoretically possible that small quantities of residual monomers can migrate from finished products.  [1] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr. Environ. Assess. Manag., 14 ; 316-334.https://doi.org/10.1002/ieam.4035 [2] Korzeniowski, S. H. et al. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. 2022.https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646  Fluoropolymers should be excluded from the scope of the restriction Based on the non-toxic properties described above, fluoropolymers (including fluoroelastomers) should in our view be excluded from the scope of this restriction. We however provide additional information showing both its negligible emission and the disproportionate socio-economic impact that would be linked to its substitution.  Derogation for uses solely in industrial settings Substances used solely in industrial settings should be derogated with appropriate risk management measures at manufacturing plant level if appropriate.  Needed transition period and inclusion in the proposed derogation combined with a review clause In case the industrial use in machinery would not be derogated, we recommend a long transition period of 13,5 years to be applied based on the feedback of our survey and time needed to place the alternatives on the market at industrial level. There is currently considerable uncertainty whether or not suitable alternative can be Implemented at industrial level within the proposed transition periods. The restriction should therefore include a review clause and process whereby it may be evaluated whether or not the alternatives could be successfully placed on the market potentially allowing if needed extension of those transition periods. |
| Answer to specific info request 1:  This comment is related to the following use: Plastic components containing PFAS used in the Engineering Polymer Shapes for Machining Association industry. The following fluoropolymers have been reported as used in engineering polymer shapes for machining: • PTFE (EC number: 618-337-2; CAS number: 9002-84-0) • PFA (EC number: 682-550-7; CAS number: 26655-00-5) The applications where these substances are used include: • Wide range of applications (automotive/chemical industries/food contact/medical/parts in machines); • PTFE as lubricant for semi-finished products. The technical application of the products; • PTFE based coatings needed in a wide range of tooling systems. Main functions: lubrication and/or chemical resistance; polymer; as part of complex products. Use/application: industrial applications (chemical industry); food contact materials & packaging; and electronics and semiconductors. Derogation is therefore partially considered for equipment for food and feed production, but many other machinery applications are impacted. We suggest to provide a derogation for industrial applications/machinery. |
| Answer to specific info request 2:  Fluoropolymers being very stable an in the polymeric form, migration is assumed to be negligible. One reference that could be taken is the OECD exposure scenario document for plastics, whereby fluoropolymers would very much behave as polymeric impact modifiers. Releases during landfilling are assumed as 0% [3]. Residual monomer content is below 1 ppm and oligomer content considered to be negligible [4,5]. [3] OECD Environment Health and Safety Publications (2009), Series on Emission Scenario Documents No. 3, Emission Scenario Document Plastics additves, https://www.oecd-ilibrary.org/docserver/9789264221291-en.pdf?expires=1694011368&id=id&accname=guest&checksum=511DD8B4F91DB362643FB439D0FFFC79 ] [4] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr. Environ. Assess. Manag., 14 ; 316-334. https://doi.org/10.1002/ieam.4035 [5] Korzeniowski, S. H. et al. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. 2022. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646 |
| Answer to specific info request 5:  5.1 Volumes of fluoroelastomers used in engineering polymers According to the study conducted by Conversio on behalf of ProK [6], the total amount of fluoropolymer materials sold to European product manufactures is estimated to be 40 Kt/year in 2020, whereof 9% are used in a category including additives, compounding, engineering polymers, and other minor applications. [6] Fluoropolymer Waste in Europe 2020 – End-of-life (EOL) Analysis of Fluoropolymer Applications, Products and Associated Waste Streams." Final Report Made on Behalf of pro-K, Conversio. July 2022. URL: https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf 5.2. Related emissions during converting and service life Concerning the fluoropolymer manufacturing stage, the Fluoropolymers Product Group (FPG) of Plastics Europe established a program focusing on the emission reduction of non-polymeric PFAS chemicals from European fluoropolymer manufacturing, including average emission targets, promoting state-of-the-art technologies to minimize emissions and a commitment to inform downstream users of fluoropolymers on their safe handling of fluoropolymer resins [7]. During the masterbatching, compounding and converting stage, the spillage of pellets is negligeable. There is only presence of dustiness; although air filters reduce the risk of emitting dust, as well as the presence of filters in water drains prevents the emission into water. Various converting processes are involved, including extrusion, injection molding, and direct forming, that are essential for shaping materials. These methods operate within specific temperature ranges, with extrusion typically occurring at 200°C or below, depending on the application. Standard extrusion processes adhere to temperature guidelines provided by resin suppliers, with maximum operation temperatures varying between 100-160°C or even up to 300°C for specific materials. These processes are critical in the manufacturing industry, facilitating the production of a wide range of products with precision and efficiency. During service life, the potential emissions are considered to be negligible given the low migration rate from the polymeric matrix. Moreover, the risk of emissions during the end-of-life is low if properly handled. The materials under consideration exhibit remarkable stability and environmentally friendly attributes, as they are chemically inert and non-degradable, placing them in the category of low concern for environmental impact. Given also the glassy nature of fluoropolymers, leaching of residuals from those would be greatly slowed down. Fluoropolymers being firmly bound in the polymer matrix, they are not expected to leach. [7] The Fluoropolymers Product Group (FPG), Plastics Europe (2023), FPG Manufacturing Programme for European Manufacturing sites, https://fluoropolymers.eu/wp-content/uploads/2023/09/FPG-Manufacturing-Programme-for-European-Manufacturing-sites-Final-September-2023.pdf |
| Answer to specific info request 7:  We herewith provide an overall view of the alternatives. It is not limited to derogated application, use in machinery (industrial application) should be derogated in a generic manner. 7.1. Analysis of Alternatives PTFE is used in plastic compounds due to their low friction, chemical resistance, high temperature, resistance, electrical insulation, flame retardancy, chemical inertness, etc; which makes them hard to be substituted in many cases. For the aforementioned applications, using alternatives would lead to different products, changing the characteristics of these. Some properties of fluoropolymers make them difficult to be replaced: • Chemical Resistance: PFAS is essential in food contact material and packaging due to its outstanding chemical resistance, which ensures the safety and integrity of food products. • Unique Lubricating Properties: The lubricating properties of PFAS are only partially replaceable with non-PFAS substances, making it a key component for effective food contact applications. Some PFAS applications are reported to be partially replaceable with other tribological combinations. In some cases, PFAS can be partially replaced with alternative tribological combinations. PTFE, used to reduce friction, has possible alternatives depending on specific requirements and applications. However, those have not been fully tested yet. In other cases, PFAS are considered irreplaceable due to outstanding chemical resistance, PFAS cannot be substituted for applications requiring exceptional chemical resistance. 7.2. Time needed for substitution/potential socio-economic effects Depending on the application, the substitution could take between 5-12 years for the replacement to be deployed at industrial level. More particularly use of PTFE in engineering polymers such as PEEK, POM but also for PET and coating was estimated to take up to 12 years for substituting. 7.3. Socio-economic impact The socio-economic impact depends on the potential transition period foreseen. R&D cost is estimated at 500 k€ per company per fluoropolymer. It would therefore amount to around 15 million € for the whole sector. In case the transition would be too fast, then we should consider the whole turnover associated to PFAs to be at stake. In the scope of our study, a calculation of the turnover related to PFAS-related articles in this sector as a proportion of the total turnover, later scaled by the overall market size, yielded a figure of €107 million – or 7% of the total turnover of this industry. |