# Committee for Risk Assessment (RAC)

# Committee for Socio-economic Analysis (SEAC)

## Background Document

to the Opinion on the Annex XV dossier proposing restrictions on
**Per- and polyfluoroalkyl substances (PFASs)**

ECHA/RAC/[opinion number will be added after adoption]
ECHA/SEAC/[opinion number will be added after adoption]

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## Version history

| Version | Changes | Date |
|---|---|---|
| 1 | Original version for pre-publication | February 2023 |
| 2 | Version for Annex XV report consultation | March 2023 |
| | Summary – clarifications in summary and explanatory note on interplay with the FFF restriction proposal and other legislation | |
| | 2.4.3.3. Assessment of the restriction options – Environmental impacts of restriction options - addition of explanations for proposed and potential derogations and updated calculated numbers | |
| | 2.4.4. Assessment of the restriction options – Proportionality to the risk– update of table comparing RO1 and RO2 based on revision of chapter 2.4.3. Assessment of the restriction options –Environmental impacts | |
| 3 | Annex XV report turned into Background Document. | September 2023 |
| | Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) – 5 b. and c. “textiles used in” was deleted for clarification of the proposed restriction | |
| | Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) – 5 i. and m. were amended for clarification of the proposed restriction | |
| | Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) – 5 n. and t. were deleted as according to REACH Article 67, restrictions do not apply to manufacture, placing on the market or use of a substance in scientific research and development. The Dossier Submitters view these initially proposed derogations as covered by Article 67. | |
| | Proposed restriction - Annex XVII entry PFASs (Restriction Option 2) – 9 was updated to clarify the intended interplay with other entries and regulations. | |
| | Explanatory notes –was updated to clarify the proposed restriction entry | |
| | Chapter 1.1.4.1. Hazard, exposure/emissions and risk– Overview - Explanation of hazard for fluoropolymers was added. | |
| | Chapter 1.1.5.1. Hazard, exposure/emissions and risk – Emission to the environment– Explanation of emission calculation was added. | |
| | Chapter 1.1.5.2. Hazard, exposure/emissions and risk – Emissions from PFASs production - Reasoning for insufficient RMMs and OCs at production sites was added. | |
| | Chapter 1.1.5.3. Hazard, exposure/emissions and risk – Article and mixture manufacturing emissions – Information on RMMs and OCs was added. | |
| | Chapter 1.1.5.4. – Hazard, exposure/emissions and risk – Product use emissions - Information on RMMs and OCs was added. Footnotes of Table 1 and the section in general were updated to explain the shown emissions. | |
| | Chapter 1.1.5.6. – Hazard, exposure/emissions and risk – Conclusion on emissions - Updated based on the changes in previous sections. | |
| | Chapter 1.3.1. Baseline – Manufacture and use – Introduction and current situation– Updated to reflect new uses and uncertainties related to missing uses. Table 2 was updated to be consistent with Table 8 and 9. Footnotes in Table 3 were added to explain the presented emissions. | |
| | Chapter 2.2.1. Regulatory risk management options – Overview of current regulatory measures - Restructuring of the section to better explain how PFASs are already addressed in existing regulation. | |
| | Chapter 2.2.2. Regulatory risk management options – Discussion of possible regulatory measures – Explanations on why other regulatory measures are deemed ineffective and not practical compared to a restriction were added. | |
| | Chapter 2.2.4. Regulatory risk management options – Conclusion on the most appropriate regulatory risk management options – Updated based on the changes in previous sections. | |
| | Chapter 2.3.1. Restriction scenario(s) – Main restriction options assessed – Approach to proposing derogations was clarified. | |
| | Chapter 2.3.2. Restriction scenario(s) – Proposed restriction option– Clarifications for proposing derogation 5v on hard chrome plating were added in Table 8 and 9. | |

| Version | Changes | Date |
|---|---|---|
| | Chapter 2.4.3. Assessment of the restriction options – Environmental impacts – Approach to emission estimation was clarified. | |
| | Chapter 2.5.1. Practicability and monitorability – Practicability of restriction options– Explanation for proposing a management plan was added. | |
| | Chapter 2.5.2. Practicability and monitorability – Concentration limits – Explanations for proposing the selected concentration limits were added. | |
| | Chapter 2.5.3. Practicability and monitorability – Summary of analytical methods– Information on total fluorine measurements were added. | |
| | Chapter 2.5.4. Practicability and monitorability – Sampling strategy and approach to enforcement– Explanation of the application of concentration limits by the enforcement authorities was added. | |
| | Chapter 2.5.5. Practicability and monitorability - Sampling strategy and approach to monitoring - Information on current analytical methods for PFASs was added. | |
| | Chapter 3. Uncertainties– Information was added to clarify uncertainties relating to missing uses and possible double counting. | |
| 4 | List of Abbreviations – Minor updates. | December 2023 |
| | Summary – Updated due to the consultation on the Annex XV report. | |
| | Explanatory notes – was updated to clarify the proposed restriction entry | |
| | Chapter 1.1.1. Hazard, exposure/emissions and risk - Identity of the substance(s), and physical and chemical properties – A new study on the possible number of PFASs was added. | |
| | Chapter 1.1.4.7. Hazard, exposure/emissions and risk – Ecotoxicity – A new study on the ecotoxicological effects of PFASs was added. | |
| | Chapter 1.1.4.10. Hazard, exposure/emissions and risk - Concerns triggered by combinations of properties – A new study on environmental stock of PFASs was added. | |
| | Chapter 1.1.5. Hazard, exposure/emissions and risk - Exposure assessment – The tonnages for emission estimates were updated based on input from the consultation on the Annex XV report. | |
| | Chapter 1.1.6.1. Hazard, exposure/emissions and risk - Case-by-case assessment according to para 0.10 of Annex I to REACH – A publication on PFASs acting as a multiplier of toxicity was added. | |
| | Chapter 1.3.1. Baseline – Manufacture and use – Introduction and current situation – New sub-uses and use tonnages were added based on information from the consultation on the Annex XV report. | |
| | Chapter 1.3.2.5. Baseline - Consumer mixtures and miscellaneous consumer articles and 1.3.2.13. Construction products – Chapters were updated with information from the consultation on the Annex XV report. | |
| | Chapter 2.2.1.7. Regulatory risk management options - Cosmetic Product Regulation (Regulation (EC) No. 1223/2009) – The reasoning for the Cosmetic Product Regulation not being able to control the risks of PFASs was added. | |
| | Chapter 2.3.1. Restriction scenario(s) – Main restriction options assessed - Updated due to the consultation on the Annex XV report. | |
| | Chapter 2.4.1. Assessment of the restriction options – Economic and other impacts – An explanation of the process for cost assessment and proposing derogations was updated. For the uses of this Background Document update (cosmetics, ski wax, consumer mixtures and misceallaneous consumer articles) this was updated accordingly. | |
| | Chapter 2.4.3. Assessment of the restriction options – Environmental impacts – The approach to the environmental impact assessment was revised. | |
| | Chapter 2.4.4.1. Assessment of the restriction options -Comparison of different restriction options – An explanation of the process for assessing effectiveness and costs of the restriction were added and applied for the uses of this Background Document (see above). | |
| 5 | Chapter 1.3.1. Baseline – Manufacture and use – Introduction and current situation – Minor updates. | February 2024 |
| | Chapter 2.4.1. Assessment of the restriction options – Economic and other impacts, 2.4.3. Environmental impacts and 2.4.4. Proportionality to the | |

| Version | Changes | Date |
|---|---|---|
| | risk – Chapters were updated based on new information from the consultation on the Annex XV report. | |
| 6 | Proposed restriction entry - Adjusted due information from the consultation on the Annex XV report. | April 2024 |
| | Explanatory note - Updated due to information from the consultation on the Annex XV report. | |
| | Chapter 1.1.1. Hazard, exposure/emissions and risk - Identity of the substance(s), and physical and chemical properties – Additional paragraphs added to describe similarities and differences between FPs and PFPEs. | |
| | Chapter 1.3.1. Baseline – Manufacture and use – Introduction and current situation – Table 2 updated based on input received in the consultation on the Annex XV report for the sectors TULAC, FCM and petroleum & mining. | |
| | Chapter 2.4.1. Assessment of the restriction options – Economic and other impacts – Updated based on input received in the consultation on the Annex XV report for the sectors TULAC and petroleum & mining. | |
| | Chapter 2.4.3.2. Assessment of the restriction options – Baseline environmental impacts – Numbers in chapter updated based on input received in the consultation on the Annex XV report for the sectors TULAC, FCM and petroleum & mining. | |
| | Chapter 2.4.3.3. Assessment of the restriction options – Environmental impacts of restriction options – Numbers and text on derogations in chapter updated based on input received in the consultation on the Annex XV report for the sectors TULAC and petroleum & mining. | |
| | Chapter 2.4.4. Assessment of the restriction options – Proportionality to the risk – Updated based on input received in the consultation on the Annex XV report for the sectors TULAC and petroleum & mining. | |
| | Chapter 2.4.1. Assessment of the restriction options – Economic and other impacts, 2.4.3. Environmental impacts and 2.4.4. Proportionality to the risk – Updated based on input received in the consultation on the Annex XV report for the sector FCM. | |
| 7 | Proposed restriction entry - Adjusted due information from the consultation on the Annex XV report. | July 2024 |
| | Explanatory note - Updated due to information from the consultation on the Annex XV report. | |
| | Chapter 1.1.5. Hazard, exposure/emissions and risk – Exposure assessment – Emission numbers in Table 1 updated based on revised sectors. | |
| | Chapter 1.3.1. Baseline – Manufacture and use – Introduction and current situation – Table 2 updated based on input received in the consultation on the Annex XV report for the sectors application of fluorinated gases and construction. | |
| | Chapter 1.3.2. Baseline – Manufacture and use – Market developments Minor updates on market information. | |
| | Chapter 2.2.1. Regulatory risk management options – Overview of current regulatory measures – Updates based on changes in regulations. | |
| | Chapter 2.3.1. Restriction scenario(s) – Main restriction options assessed - Updated due to the consultation on the Annex XV report. | |
| | Chapter 2.4.1. Assessment of the restriction options – Economic and other impacts – Updated based on input received in the consultation on the Annex XV report for the sectors applications of fluorinated gases and construction. | |
| | Chapter 2.4.3.2. Assessment of the restriction options – Baseline environmental impacts and 2.4.3.3. Environmental impacts of restriction options – Numbers and text on derogations in chapter updated based on input received in the consultation on the Annex XV report for the sectors applications of fluorinated gases and construction. | |
| | Chapter 2.4.4. Assessment of the restriction options – Proportionality to the risk – Updated based on input received in the consultation on the Annex XV report for the sectors applications of fluorinated gases and construction. | |
| 8 | Summary – Proposed restriction entry and explanatory notes were updated due to the consultation on the Annex XV report. | October 2024 |

| **Version** | **Changes** | **Date** |
|---|---|---|
| | Section 1.1.5. Hazard, exposure/emissions and risk - Exposure assessment – Table 1 was updated. | |
| | Section 1.3.1. Baseline – Manufacture and use – Introduction and current situation – Table 2 was updated. | |
| | Section 2.4.1.1. Assessment of the restriction options - Economic impacts on producers and customers and other impacts (e.g. employment losses) - changes in Table 8 were made. | |
| | Section 2.4.3.2. Assessment of the restriction options - Baseline environmental impacts and Section 2.4.3.3. Environmental impacts of restriction options - corrections of emission based on input from the consultation on the Annex XV report were made. | |
| | Section 2.4.3.3. Assessment of the restriction options - Environmental impacts of restriction options – Chapter was updated based on information received in the consultation on the Annex XV report. | |
| | Section 2.4.4.1. Assessment of the restriction options - Comparison of different restriction options – Chapter was updated based on information received in the consultation on the Annex XV report. | |
| 9 | Summary – Proposed restriction entry and explanatory notes were updated due to the consultation on the Annex XV report. | November 2024 |
| | Section 1.1.5. Hazard, exposure/emissions and risk - Exposure assessment – Table 1 was updated. | |
| | Section 1.3.1. Baseline – Manufacture and use – Introduction and current situation – Tables 2 and 3 were updated. | |
| | Section 1.3.2.14 Lubricants was revised based on information received in the consultation on the Annex XV report | |
| | Section 1.3.2.16 was added based on information received in the consultation on the Annex XV report | |
| | Section 2.4.1.1. Assessment of the restriction options - Economic impacts on producers and customers and other impacts (e.g. employment losses) - changes in Tables 8 and 9 were made in relation to medical devices, lubricants and printing applications | |
| | Section 2.4.3.2. Assessment of the restriction options - Baseline environmental impacts and Section 2.4.3.3. Environmental impacts of restriction options – tonnage and emissions have been updated based on input from the consultation on the Annex XV report. | |
| | Section 2.4.3.3. Assessment of the restriction options - Environmental impacts of restriction options – section was updated based on information received in the consultation on the Annex XV report with regard to medical devices, lubricants and printing applications. The information on transport was updated to align with the Annexes | |
| | Section 2.4.4.1. Assessment of the restriction options - Comparison of different restriction options – Chapter was updated based on information received in the consultation on the Annex XV report. | |
| 10 | Proposed restriction - Annex XVII entry PFASs (Restriction Option 2): New information added with regard to sealing applications and small corrections implemented with regard to printing applications. | December 2024 |
| | Section 1.1.5.1. – Emission to the environment - Updated based on input received in the consultation on the Annex XV report for the sector sealing applications | |
| | Section 1.3 – Baseline - Updated based on input received in the consultation on the Annex XV report for the sector sealing applications | |
| | Section 2.3.1. – Main restriction options assessed - Updated based on input received in the consultation on the Annex XV report for the sector sealing applications | |
| | Section 2.4.1. – Assessment of the restriction options – Economic and other impacts – Updated based on input received in the consultation on the Annex XV report for the sector sealing applications and small corrections implemented with regard to printing applications. | |
| | Section 2.4.3.2. Assessment of the restriction options - Baseline environmental impacts and Section 2.4.3.3. Environmental impacts of restriction options – Updated based on input received in the consultation on the Annex XV report for the sector sealing applications and small | |

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| | corrections implemented with regard to printing applications and medical devices | |
| | Section 2.4.4.1. Assessment of the restriction options - Comparison of different restriction options – Updated based on input received in the consultation on the Annex XV report for the sector sealing applications and small corrections implemented with regard to printing applications and medical devices | |
| 11 | Proposed restriction - Annex XVII entry PFASs: Derogations added regarding electronics and semiconductors, printing applications, machinery and other medical applications, including explanatory notes based on input received in the consultation on the Annex XV report | February 2025 |
| | Section 1.1.5.4. Product use emissions – values in table 1 updated regarding electronics and semiconductors, printing applications, machinery and other medical applications based on input received in the consultation on the Annex XV report | |
| | Section 1.3. Baseline – Table 2 updated regarding sub-uses on electronics and semiconductors; values in Table 3 updated regarding electronics and semiconductors, printing applications, machinery and other medical applications based on input received in the consultation on the Annex XV report | |
| | Section 1.3.2. Information for Electronics and semiconductors, machinery and other medical applications updated based on input received in the consultation on the Annex XV report | |
| | Section 2.4.1.1. Economic impacts on producers and customers and other impacts (e.g. employment losses) – Table 8 and 9 updated regarding electronics and semiconductors, printing applications, machinery and other medical applications based on input received in the consultation on the Annex XV report | |
| | Section 2.4.4.1. Comparison of different restriction options – updated regarding electronics and semiconductors, printing applications, machinery and other medical applications based on input received in the consultation on the Annex XV report | |
| 12 | Proposed restriction - Annex XVII entry PFASs: Derogations added regarding military applications and explosives based on input received in the consultation on the Annex XV report | March 2025 |
| | Section 1.1.5.4. Product use emissions – values in table 1 corrected regarding other medical applications and updated regarding military applications and explosives based on input received in the consultation on the Annex XV report | |
| | Section 1.3. Baseline – Table 2 updated regarding sub-uses on military applications and explosives; values in Table 3 updated regarding military applications and explosives based on input received in the consultation on the Annex XV report | |
| | Section 1.3.2. Information for military applications and explosives added based on input received in the consultation on the Annex XV report | |
| | Section 2.4.1.1. Economic impacts on producers and customers and other impacts (e.g. employment losses) – Tables 8 and 9 corrected regarding medical devices and other medical applications and updated regarding military applications and explosives based on input received in the consultation on the Annex XV report | |
| | Section 2.4.4.1. Comparison of different restriction options – corrected regarding medical devices and other medical applications and updated regarding military applications and explosives based on input received in the consultation on the Annex XV report | |
| 13 | Whole document: editorial/consistency related corrections (e.g. typos, updates of references to other sections or Annexes, naming of sectors, etc.) | June 2025 |
| | Summary – updated to reflect updates in the background document based on the comments received in the consultation on the Annex XV report | |
| | Proposed restriction - Annex XVII entry PFASs: Inclusion of new derogations based on sectors and horizontal topics assessed in this version of the BD; ordering of derogations adjusted to reflect presented order of | |

| Version | Changes | Date |
|---|---|---|
| | sectors in this and other parts of the background document. Also the explanatory note has been adjusted accordingly. | |
| | Section 1.1.5.4. Product use emissions – values in table 1 corrected updated regarding manufacture and technical textiles based on input received in the consultation on the Annex XV report. Total emissions value updated. | |
| | Section 1.1.5.6. Summary on emissions – updated based on data in table 1 | |
| | Section 1.3. Baseline – Table 2 updated regarding sub-uses of technical textiles; values in Table 3 updated regarding manufacture and technical textiles based on input received in the consultation on the Annex XV report. Table 4 updated based on new tonnage and emission estimates after the consultation on the Annex XV report. | |
| | Section 1.3.2. Information for technical textiles added based on input received in the consultation on the Annex XV report | |
| | Section 2.2.1.9. Examples of legislation outside the EU – updated based on comments received in the consultation on the Annex XV report | |
| | Section 2.2.3. Active Substances – updated based on information received in the consultation on the Annex XV report | |
| | Section 2.3.1. Main restriction options assessed – updated to reflect the assessment of alternative restriction options (RO3) | |
| | Section 2.4.1.1. Economic impacts on producers and customers and other impacts (e.g. employment losses) – Tables 10 and 11 updated regarding technical textiles based on input received in the consultation on the Annex XV report; subsection on cumulative impacts and Overarching impacts on trade and competitiveness added; | |
| | Section 2.4.2. Human health impacts – updated based on information received in the consultation on the Annex XV report | |
| | Section 2.4.3. Environmental impacts – updated to provide further clarification on the approach chosen by the Dossier Submitters and with information on technical textiles (Tables 13 and 14); | |
| | Section 2.4.4. Proportionality to the risk – updated based on information received in the consultation on the Annex XV report | |
| | Section 2.5 Practicability and monitorability – updated based on information received in the consultation on the Annex XV report | |
| | Chapter 3. Uncertainties – updated to reflect updates in the background document and to align with changes in Annex F. | |
| 14 | Summary – updated to reflect updates in the background document based on the comments received in the consultation on the Annex XV report | June 2025 |
| | Proposed restriction - Annex XVII entry PFASs: Inclusion of new derogations based on sectors and horizontal topics assessed in this version of the BD. Also the explanatory note has been adjusted accordingly. | |
| | Section 1.1.5.4. Product use emissions – values in table 1 corrected updated regarding broader industrial uses based on input received in the consultation on the Annex XV report. Total emissions value updated. | |
| | Section 1.1.5.6. Summary on emissions – updated based on data in table 1 | |
| | Section 1.3. Baseline – Table 2 updated regarding sub-uses of broader industrial uses; values in Table 3 updated regarding broader industrial uses based on input received in the consultation on the Annex XV report. | |
| | Section 1.3.2. Information for broader industrial uses added based on input received in the consultation on the Annex XV report | |
| | Section 2.4.1.1. Economic impacts on producers and customers and other impacts (e.g. employment losses) – Tables 10 and 11 updated regarding broader industrial uses based on input received in the consultation on the Annex XV report. | |
| | Section 2.4.2. Human health impacts – updated based on information received in the consultation on the Annex XV report | |
| | Section 2.4.3. Environmental impacts – updated with information on broader industrial uses (Tables 13 and 14); | |
| | Section 2.4.4. Proportionality to the risk – updated based on information received in the consultation on the Annex XV report | |

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|---|---|---|
| | 4. Conclusion – updated to reflect updates in the background document based on the comments received in the consultation on the Annex XV report | |

# TABLE OF CONTENTS

## TABLES

## FIGURES

## LIST OF ABBREVIATIONS

Note: Due to the large scope of the dossier, some abbreviations in this list appear more than once, since they can have different meanings. Also, in a few cases different abbreviations can have the same meaning. In both cases, abbreviation and meaning are written in *Italics*. The abbreviations can be easily deduced from the context.

| Acronym | Explanation |
|---|---|
| 2-BTP | 2-bromo-3,3,3-trifluoro-1-propene |

| **Acronym** | **Explanation** |
|---|---|
| 3-D | Three-dimensional |
| 3F | Fluorine-free foam |
| 4:2 Cl-PFESA | 4:2 Cl-polyfluorinated ether sulfonate |
| 4:2 FTMA | 4:2 Fluorotelomer methacrylate |
| 4:2 FTO | 4:2 Fluorotelomer olefin |
| 4:2 FTSA | 4:2 Fluorotelomer sulfonic acid |
| 6:2 Cl-PFESA | 6:2 Chlorinated polyfluorinated ether sulfonate |
| 6:2 diPAP | 6:2 Fluorotelomer phosphate diester |
| 6:2 FTOH | 6:2 Fluorotelomer alcohol |
| 6:2 FTS | 6:2 Fluorotelomer sulfonate |
| 6:2 FTSA | 6:2 Fluorotelomer sulfonic acid |
| 6:2/8:2 diPAP | 6:2/8:2 Fluorotelomer phosphate diester |
| 7:3 FTCA | 7:3 Fluorotelomer carboxylic acid |
| 8:2 Cl-PFESA | 8:2 Cl-polyfluorinated ether sulfonate |
| 8:2 diPAP | Bis[2-(perfluorooctyl)ethyl] phosphate |
| 8:2 FTOH | 8:2 Fluorotelomer alcohol |
| 8:2 FTSA | 8:2 Fluorotelomer sulfonic acid |
| 8:2 monoPAP | 8:2 Fluorotelomer phosphate monoester |
| 8:2 PTrMeOSi | 8:2 Polyfluoroalkyl trimethoxysilane |
| 8:2/10:2 diPAP | 8:2/10:2 Fluorotelomer phosphate diester |
| 9Cl-PF3ONS | 9-Chlorohexadecafluoro-3-oxanonane-1-sulfonic acid |
| 10:2 diPAP | 10:2 Fluorotelomer phosphate diester |
| ABS | Anti-lock Braking System |
| AC | Airconditioning |
| AC | Alternating Current |
| ADAS | Advanced Driver Assistance Systems |
| ADME | (Process of) Absorption, distribution, metabolism, and excretion |
| ADONA | Ammonium 4,8-dioxa-3H-perfluorononanoate, 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid] |
| AEC | Anion Exchange Capacity |
| AFFF | Aqueous Film-Forming Foam |
| AFT | Acrylic Foam Tape |
| AIX | Anion Exchange |
| ALK | Alkaline water electrolysis |
| ALP | Alkaline phosphatase |
| ALT | Alanine transferase |
| AMA | Amphibian Metamorphosis Assay (OECD TG 231) |
| AoA | Analysis of Alternatives |
| AOF | Adsorbable Organic Fluorine |
| AOP | Advanced Oxidation Process |
| APC | Air Pollution Control |

| **Acronym** | **Explanation** |
|---|---|
| APFO | Ammonium perfluorooctanoate |
| API | Active Pharmaceutical Ingredient |
| AR | Androgen Receptor |
| AR-AFFF | Alcohol Resistant-Aqueous Film Forming Foam |
| ARFF | Aircraft Rescue & Firefighting |
| AR-FFFP | Alcohol-Resistant Film-Forming Fluoro-Protein |
| ASBT | Apical Sodium-Dependent Bile Salt Transporter |
| AST | Aspartate transferase |
| ATC | Anatomical Therapeutic Chemical |
| ATSDR | Agency for Toxic Substances and Disease Registry |
| BAC | Biological Activated Carbon |
| BAF | Bioaccumulation Factor |
| BAU | Business As Usual |
| BCCC | Basel Coordination Centre for Africa |
| BCF | Bioconcentration Factor |
| $BCF_{SS}$ | Bioconcentration Factor at steady state |
| BIONIC | Bioconcentration Model for Ionogenic Organic Compounds |
| BMF | Biomagnification Factor |
| BMI | Bodymass Index |
| BN | Boron Nitrate |
| BOD | Biological Oxygen Demand |
| BP | Biocidal Product |
| BPR | Biocidal Products Regulation |
| BREF BAT | Best Reference Best Available Technique |
| br-PFOS | Branched PFOS |
| BSA | Bovine Serum Albumine |
| BUN | Blood Urea Nitrogen |
| BW | Body Weight |
| C4-FN | Heptafluoroisobutyonitrile |
| C5-FK | 1,1,1,3,4,4,4-Heptafluoro-3-(trifluoromethyl)-2-butanone |
| C6/C6 PFPiA | C6/C6 Perfluorophosphinic acid |
| C6/C8 PFPiA | C6/C8 Perfluorophosphinic acid; Perfluorohexylperfluorooctyl phosphinate |
| C6/C10 PFPiA | Perfluorohexylperfluorodecyl phosphinic acid |
| C6/C12 PFPiA | C6/C12 Perfluorophosphinic acid |
| C8/C8 PFPiA | C8/C8 Perfluorophosphinic acid |
| C8/C10 PFPiA | C8/C10 Perfluorophosphinic acid |
| CAA | Civil Aviation Authority |
| CAF | Compressed Air Foam |
| CAGR | Compound Annual Growth Rate |
| CAR | Constitutive Androstane Receptor |

| Acronym | Explanation |
|---|---|
| Carc. | Carcinogenicity |
| CAS | Chemical Abstracts Service |
| CASRN | Chemical Abstracts Service Registry Number |
| CBT | Closed Bottle Test |
| CBRN | Chemical, biological, radiological and nuclear |
| CCM | Catalyst-coated Membrane |
| C-E | Cost-effectiveness |
| CE marking | European Conformity Marking; French: Conformité Européenne |
| CEN | Chicken Embryonic Neuronal |
| CEPI | Confederation of European Paper Industries |
| CEWEP | Confederation of European Waste-to-Energy Plants |
| CFC | Chlorofluorocarbon |
| CfE | Call for Evidence |
| ChG | Choriogenin |
| CHO | Chinese Hamster Ovary |
| CI | Confidence Interval |
| CIC | Combustion Ion Chromatography |
| CLH | Harmonised Classification and Labelling |
| CLP | Classification, Labelling and Packaging |
| Cl-PFESA | Chlorinated Polyfluorinated Ether Sulfonate |
| CMR | Carcinogenic, Mutagenic and Toxic for Reproduction |
| COD | Chemical Oxygen Demand |
| COF | Coefficients of Friction |
| COP | Conference of the Parties |
| COVID-19 | Coronavirus Disease 2019 |
| CR | Neoprene Rubber (Chloroprene Rubber) |
| CRT | Cathode-Ray Tube |
| CSS | Chemicals Strategy for Sustainability |
| CTD | Characteristic Travel Distance |
| CTFE | Chlorotrifluoroethylene |
| CTV | Chronic Toxicity Value |
| CYP4a | Cytochrome P4504a |
| CYP19 | Cytochrome P-19 |
| d | Days |
| Da | Dalton |
| DC | Direct Current |
| DE | Germany |
| DHT | 5 Alpha-Androstan-17-beta-ol-3-one |
| DIN | German Institute for Standardisation |
| DIY | Do It Yourself |
| DK | Denmark |

| **Acronym** | **Explanation** |
|---|---|
| DMEL | Derived Minimal Effect Level |
| DMSO | Dimethylsulphoxide |
| DMW | Distribution Ratios for Membrane–water |
| DNEL | Derived No-Effect Level |
| DOC | Dissolved Organic Carbon |
| DoD | Department of Defense |
| DONA | Dodecafluoro-3H-4,8-dioxanonanoic acid |
| *dpf* | *Days Post Fertilization* |
| *DPF* | *Diesel Particulate Filter* |
| DPW | Distribution Ratios for Protein–water |
| DS | Dossier Submitters |
| dw | Dry Weight |
| DWD | Drinking Water Directive |
| DWR | Durable Water Repellent |
| E2 | Estrogen/17-beta-estradiol |
| EA | Endocrine Activity |
| EbC50 | Effect Concentration Algal Biomass |
| EC | European Commission |
| EC50 | Effect Concentration |
| *ECF* | *Edible Part Concentration Factor* |
| *ECF* | *Electrochemical Fluorination* |
| ECHA | European Chemicals Agency |
| ECNI-MS | Electron Capture Negative Ion Mass Spectrometry |
| ECOS | Environmental Coalition on Standards |
| ECTFE | Ethylenechlorotrifluoroethylene |
| ED | Endocrine Disruption |
| EDA | Electronic Design Automation |
| ED EG | Endocrine Disruptor Expert Group (ECHA advisory panel) |
| ED-RIA | Direct Equilibrium Dialysis Followed by Radioimmunoassay |
| EEA | European Economic Area |
| EEA-NH4 | Ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate |
| EEE | Electrical and Electronic Equipment |
| EEIT | Electrical Engineering and Information Technology |
| EFCTC | The European Fluorocarbons Technical Committee |
| EFSA | European Food Safety Authority |
| EFSA CONTAM | European Food Safety Authority- Panel on Contaminants in the Food Chain |
| EFTC | European Fluorocarbons Technical Committee |
| EGR | Exhaust gas recirculation |
| EIF | Entry Into Force |
| ELISA | Enzyme-Linked Immunosorbent Assay |

| Acronym | Explanation |
|---|---|
| ELV | End of Life of Vehicles |
| EMDN | European Medical Device Nomenclature |
| EMEA | Europe, Middle East and Africa |
| EO | Ethylene oxide |
| EOF | Extractable Organic Fluorine |
| EOL | End of Life |
| *EPA* | *Environmental Protection Agency* |
| *EPA* | *Efficiency Particulate Air* |
| EPDM | Ethylene propylene diene monomer |
| EPR | Extended Producer Responsibility |
| ePTFE | Expanded PTFE |
| EQSD | Environmental Quality Standards Directive |
| ER | Estrogen Receptor(s) |
| ERC | Environmental Release Category |
| ErC50 | Effect Concentration Algal Growth |
| ESD | OECD Emission Scenario Document |
| ESI | Electrospray Ionisation |
| ESP | Electronic Stability Program |
| EtFASAs | N-ethyl perfluoroalkane sulfonamides |
| ETFBO | 4-Ethoxy-1,1,1-trifluoro-3-buten-2-one |
| ETFE | Ethylene tetrafluoroethylene |
| EtFOSA | N-ethyl perfluorooctane sulfonamide |
| EtFOSAA | N-ethyl perfluorooctane sulfonamidoacetic acid |
| EtFOSE | N-ethyl perfluorooctanesulfonamidoethanol |
| ETSA | European Textile Services Association |
| EU | European Union |
| EU-27 | European Union: 27 countries |
| EU-28 | European Union: 28 countries |
| EUDAMED | European Database on Medical Devices |
| EUREAU | European Federation of National Associations of Water Services |
| Eurofeu | European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles |
| EURITS | European Union for Responsible Treatment of Special Waste |
| EV | Electric Vehicle |
| EVA | Ethylene vinyl acetate |
| f | Females |
| F0 | Parental Generation |
| FABP | Fatty acid binding protein |
| FASA | Perfluoroalkane sulphonamide |
| FASE | Perfluoroalkyl sulfonamidoethanol |
| FBG | Fasting Blood Glucose |

| Acronym | Explanation |
|---|---|
| FCCC | Fire Fighting Foam Coalition (US association) |
| FC-3284 | 2,2,3,3,5,5,6,6-Octafluoro-4-(trifluoromethyl)morpholine |
| FC-807 | Ammonium bis(N-ethyl-2-perfluorooctylsulfonaminoethyl)phosphate |
| FCM | Food Contact Material |
| FCS | Food Contact Substance |
| F-DIOX | Ammonium difluoro{[2,2,4,5-tetrafluoro-5-(trifluoromethoxy)-1,3-dioxolan-4-yl]oxy}acetate |
| FEC | Federation of European manufactures of cookware and cutlery |
| FEP | Fluorinated ethylene propylene |
| FEPM | Tetrafluoroethylene propylene |
| fEPSP | Field Excitatory Postsynaptic Potential |
| FEVE | Fluoroethylene Vinyl Ether Resin |
| FFFC | Fire Fighting Foam Coalition |
| FFFP | Fluoroprotein Foam Concentrates and Film Forming Fluoro-protein |
| FFKM | Perfluoroelastomers |
| F-gas | Fluorinated Gas |
| FHEA | Perfluorohexyl ethanoic acid |
| FI | Fasting Insulin |
| FIS | International Ski Federation |
| FK | Fluoroketones |
| FK-5-1-12 | 1,1,1,2,2,4,5,5,5-nonafluoro-4-(trifluoromethyl)-3-pentanone |
| FKM | Family of Fluorocarbon-based Fluoroelastomer Materials |
| FMV | Swedish Defence Materiel Administration |
| FOB | Functional Observational Battery |
| FOSA | Perfluorooctane sulfonamide |
| FP | Fluoro Protein |
| FPA Australia | Fire Protection Association Australia |
| FPAR | Fluoro-Protein Alcohol-Resistant |
| FR | France |
| FRCF | Foliage to Root Concentration Factor |
| FRV | Fire Rescue Victoria, Australia |
| FSDT | Fish Sexual Development Test (OECD TG 234) |
| FSH | Follicle Stimulating Hormone |
| FTA | Fluorotelomer acrylate |
| FTAL | Fluorotelomer aldehyde |
| FTCA | Fluorotelomer carboxylic acid |
| FTEO | Fluorotelomer ethoxylate |
| FTIR | Fourier transform infrared (Spectroscopy) |
| FTI | Fluorotelomer iodide |
| FTMAf | Fluorotelomer methacrylate |
| FTOH | Fluorotelomer alcohol |

| **Acronym** | **Explanation** |
|---|---|
| FTO | Fluorotelomer olefin |
| FTS | Fluorotelomer sulfonate |
| FTSA | Fluorotelomer sulfonic acid |
| FTTAoS | Fluorotelomer thioether amido sulfonate |
| FTUCA | Fluorotelomer unsaturated carboxylic acid |
| FVQM | Fluorosilicones |
| GAC | Granular Activated Carbon |
| GAC filter | Granular Activated Carbon Filter |
| GC | Gas Chromatography |
| GDL | Gas Diffusion Layer |
| GDP | Gross Domestic Product |
| GFK | Glass Fiber Reinforced Composite Material |
| GGMs | Gaussian Graphical Models |
| GHG | Greenhouse Gas |
| GHz | Gigahertz |
| GI | Gastrointestinal |
| GLP | Good Laboratory Practice |
| GRP | Glass-fiber Reinforced Plastic |
| GSAF | Grass-soil Accumulation Factor |
| GSI | Gonadosomatic Index |
| GST | Glutathione S-transferase |
| GWP | Global Warming Potential |
| H4-PFOS | 6:2 fluorotelomer sulfonate |
| HAC | Hazardous Air Contaminant |
| HAP | Hazardous Air Pollutant |
| HC | Hydrocarbon |
| HCFC | Hydrochlorofluorocarbon |
| HCWH | Health Care Without Harm |
| HDL | High-density Lipoprotein |
| HDL-C | High-density Lipoprotein Cholesterol |
| HDPE | High-density Polyethylene |
| HEK293 | Human Embryonic Kidney 293 |
| HEPA | High Efficiency Particulate Air (filter) |
| HF | Hydrogen Fluoride |
| HFC | Hydrofluorocarbon |
| HFC-4310-mee | Reaction mass of (R, R)-1,1,1,2,2,3,4,5,5,5-decafluoropentane and (S, S)-1,1,1,2,2,3,4,5,5,5-decafluoropentane |
| HFE | Hydrofluoroether |
| HFIP | Hexafluoroisopropanol |
| HFO | Hydrofluoroolefin |
| HFP | Hexafluoropropylene |

| **Acronym** | **Explanation** |
|---|---|
| HFPO | Trifluoro(trifluoromethyl)oxirane; Hexafluoro-1,2-epoxypropane; 2,2,3-Trifluoro-3-(trifluoromethyl)oxirane |
| HFPO-DA | Hexafluoropropylene oxide dimer acid, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid |
| HFPO-TA | Hexafluoropropylene oxide trimer acid, 2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-(heptafluoropropoxy)propoxy]propanoic acid |
| HFPO-TeA | Hexafluoropropylene oxide tetramer acid |
| HI | Hazard Index |
| hpf | Hours Post Fertilization |
| HPL | High Pressure Laminate |
| HPG | Hypothalamus-Pituitary-Gonad |
| HPT | Hypothalamus-Pituitary-Thyroid |
| HR-MS | High Resolution Mass Spetrometry |
| HSI | Hepatosomatic Index |
| HVACR | Heating, Ventilation, Air Conditioning and Refrigeration |
| HWI | Hazardous Waste Incinerators |
| IARC | The International Agency for Research on Cancer |
| IATF | International Automotive Task Force |
| IBCs | Intermediate Bulk Containers |
| IC | Ion Chromatography |
| IC50 | Inhibitory Concentration |
| ICAO | International Civil Aviation Organization |
| IEC | International Electrotechnical Commission |
| IED | Industrial Emissions Directive |
| IEM | Ion Exchange Membrane |
| IGBT | Insulated Gate Bipolar Transistor |
| IMO | International Maritime Organization |
| INCI | International Nomenclature Cosmetic Ingredient |
| Intertanko | International Association of Independent Tanker Owners |
| IP | Intellectual Property |
| IPCC | Intergovernmental Panel on Climate Change |
| IPCS | International Programme on Chemical Safety |
| IPEN | International Pollutants Elimination Network |
| IPRCO | Interstate Technology and Regulation Council |
| IS | Iceland |
| ISO | International Organization for Standardization |
| *IT* | *Information Technology* |
| *IT* | *Italy* |
| ITRC | Interstate Technology and Regulatory Council |
| IVDR | In Vitro Diagnostic Regulation |
| IX | Ion Exchange |
| $K_d$ | Sediment/water distribution coefficient |

| **Acronym** | **Explanation** |
|---|---|
| KEMI | Swedish Chemicals Agency; Swedish: Kemikalieinspektionen |
| kg | Kilogram |
| $K_{OC}$ | Organic carbon-water partition coefficient |
| $K_{OW}$ | Octanol-water partition coefficient |
| $K_{PW}$ | Protein water distribution coefficient |
| KPFBS | Potassium perfluorobutane sulfonate |
| L | Lactation Effects |
| Lact. | Lactation |
| LAN | Local Area Network |
| LAST | Large Atmospheric Storage Tank |
| LBD | Ligand Binding Domain |
| *LC* | *Long-chain* |
| *LC* | *Liquid chromatography* |
| *LC* | *Lethal Concentration* |
| LC50 | Lethal Concentration |
| LCD | Liquid Crystal Display |
| LDL | Low-Density Lipoprotein |
| LDL-c | Low-Density Lipoprotein Cholesterol |
| LfU | Bavarian State Ministry for the Environment and Consumer Protection |
| LH | Luteinizing Hormone |
| Li-Ion | Lithium-Ion (battery) |
| lin-PFOS | Linear PFOS |
| LLDPE | Linear Low-Density Polyethylene |
| LOAEL | Lowest Observed Adverse Effect Level |
| LOD | Limit of Detection |
| LOEC | Lowest Observed Effect Concentration |
| log $D_{\mathrm{BSAw}}$ | Base-10 logarithm of albumin–water distribution coefficients |
| log $D_{\mathrm{mpw}}$ | Base-10 logarithm of protein–water distribution coefficients |
| log $D_{\mathrm{mw}}$ | Base-10 logarithm of of membrane–water distribution coefficients |
| log $D_{\mathrm{ow}}$ | Base-10 logarithm of octanol–water distribution coefficients |
| LOQ | Limit of Quantification |
| LOX | Liquid Oxygen |
| LPPS | Liquid-phase peptide synthesis |
| LRT | Long-Range Transport |
| LRTP | Long-Range Transport Potential |
| LTP | Long-Term Potentiation |
| m | Males |
| M&A | Mergers and Acquisitions |
| MAC | Mobile Air-Conditioning |
| MDI | Metered Dose Inhaler |
| MDL | Method Detection Limit |

| **Acronym** | **Explanation** |
|---|---|
| MDR | Medical Decives Regulation |
| MEA | Membrane Electrode Assemblies |
| MeFASA | N-methyl perfluoroalkane sulphonamide |
| Me-FBSA | N-metylperfluorobutane sulfonamide |
| MeFOSA | N-methyl perfluorooctane sulfonamide |
| MeFOSAA | N-methyl perfluorooctane sulfonamidoacetic acid |
| MeFOSE | N-methyl perfluorooctane sulfonamidoethanol |
| MEK | Mitogen-Activated Protein Kinase (MAPK)/Extracellular Signal-Rregulated Kinases (ERK) Kinase |
| MetS | Metabolic Syndrome |
| MFB | Victorian Metropolitan Fire and Emergency Services Board |
| µg | Microgram |
| mg | Milligram |
| MLB | Mobile extinguishing water treatment plant (DE) |
| MoA | Mode of Action |
| MoD | Ministry of Defence |
| monoPAPs/diPAPs | Polyfluoroalkyl phosphoric acid mono-/diesters |
| MP | Medicinal Products |
| MRI | Magnetic Resonance Imaging |
| mRNA | Messenger-RNA |
| MS | Mass Spectrometry |
| MSFD | Marine Strategy Framework Directive |
| Muta. | Mutagenicity |
| MW | Molecular Weight |
| MWV | Mineralölwirtschaftsverband (German Association for Mineral Oil Industry) |
| n:2 FTI | n:2 Fluorotelomer iodide |
| n:2 FTOH | n:2 fluorotelomer alcohol |
| n:2 FTSA | n:2 fluorotelomer sulfonic acid |
| n:2 PAP | n:2 polyfluoroalkyl phosphoric acid ester, PAP |
| n.a. | Not available |
| NBR | Nitril Butadiene Rubber |
| NDAA | National Defence Authorization Act |
| N-EtFOSAA | N-Ethyl perfluorooctane sulfonamidoacetic acid |
| ng | Nanogram |
| NGO | Non-governmental Organisation |
| NHANES | National Health and Nutrition Examination Survey |
| NILU | Norwegian Institute for Air Research |
| NIVA | Norwegian Institute for Water Research |
| NK | Natural Killer |
| NL | The Netherlands |
| N-MeFOSAA | N-Methyl perfluorooctane sulfonamidoacetic acid |
| NMR | Nuclear Magnetic Resonance |

| **Acronym** | **Explanation** |
|---|---|
| NO | Norway |
| NOAEL | No Observed Adverse Effect Level |
| NOEC | No Observed Effect Concentration |
| Norflurane | 1,1,1,2-Tetrafluoroethane, also HFC-134a |
| Noviflumuron | 1-[3,5-dichloro-2-fluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)phenyl]-3-(2,6-difluorobenzoyl)urea |
| NOx | Nitrogen Oxide |
| NPS | Nano-sized Particle Fractionator |
| NPV | Net Present Value |
| NTCP | $Na^+$/Taurocholate Cotransporting Polypeptide |
| *NTS* | *Non-destructive Testing System* |
| *NTS* | *Non Target Screening* |
| OAT | Organic Anion Transporter |
| OATP | Organic Anion Transporting Polypeptide |
| OBS | p-perfluorous nonenoxybenzenesulfonate |
| Oct-1 | Octamer Motif-Binding Factor 1 |
| OECD | Organisation for Economic Co-operation and Development |
| OEM | Original Equipment Manufacturer |
| OLED | Organic Light-Emitting Diode |
| ORC | Organic Rankine Cycle |
| OSPAR | The Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic |
| *PA* | *Polyamide* |
| *PA* | *Processing Aid* |
| PAC | Powdered Activated Carbon |
| PACF | Perfluoroalkanoyl fluoride |
| PAH | Polycyclic Aromatic Hydrocarbon |
| PAO | Poly-alpha-olefin |
| PAP | Polyfluoroalkyl phosphate ester |
| PASF | Perfluroalkane sulfonyl fluoride |
| PAVE | Copolymer of tetrafluoroethylene and a perfluoroalkylvinylether |
| PBSF | Perfluorobutane sulfonyl fluoride |
| *PBT* | *Persistent, Bioaccumulative and Toxic* |
| *PBT* | *Polybutylene terephthalate* |
| PBTK | Physiologically Based Toxicokinetic |
| PC | Polycarbonate |
| PCB | Polychlorinated biphenyl |
| PCTFE | Polychlorotrifluoroethylene |
| PE | Polyethylene |
| PEC | Predicted Environmental Concentration |
| PEEK | Polyetheretherketone |
| PEG | Polyethylene glycol |
| *PEM* | *Proton-Exchange Membrane* |
| *PEM* | *Polymer Electrolyte Membrane* |
| PEMFC | Proton-Exchange Membrane Fuel Cell |
| *PET* | *Polyethylene terephthalate* |

| **Acronym** | **Explanation** |
|---|---|
| *PET* | *Positron Emission Tomography* |
| PEVE | 1,1,2-Trifluoro-2-(pentafluoroethoxy)ethene |
| PEX | Irradiation crosslinked polyethylene |
| PF-310 | 1-[3-[4-((Heptadecafluorononyl)oxy)-benzamido]propyl]-N,N,N-trimethylammonium iodide |
| *PFA* | *Perfluoroalkoxyl polymer* |
| *PFA* | *Perfluoroalkoxy alkane* |
| PFAA | Perfluoroalkyl acid |
| PFAE | Perfluoroalkylether |
| PFAI | Perfluoroalkyl iodide |
| PFAS | Per- and Polyfluoroalkyl Substance |
| PFBA | Perfluorobutanoic acid |
| PFBPA | Perfluorobutyl-phosphonic acid; (Nonafluorobutyl)phosphonic acid |
| PFBS | Perfluorobutane sulfonic acid |
| *PFC* | *Perfluorinated compound* |
| *PFC* | *Polyfluorocarbon* |
| PFC-318 | Perfluorocyclobutane |
| PFCA | Perfluoroalkyl carboxylic acid |
| PFDA | Perfluorodecanoic acid |
| PFdiCA | Perfluoroalkyl dicarboxylic acid |
| PFdiSA | Perfluoroalkane disulfonic acid |
| PFDoDA | Perfluorododecanoic acid |
| PFDPA | Perfluorodecylphosphonic acid |
| PFDS | Perfluorodecane sulfonic acid |
| PFE alkane | Perfluoroether alkane |
| PFEA | Perfluoroether acid |
| PFECA | Perfluoroalkylether carboxylic acid |
| PFECHS | Perfluoro-4-(ethyl)cyclohexanesulfonate |
| PFEE | Perfluorodiethyl ether; Perfluoroethyl ether; 1,1,1,2,2-Pentafluoro-2-(pentafluoroethoxy)ethane |
| PFEPA | Pentafluoroethyl-phosphonic acid; Perfluoroethyl phosponic acid; (Pentafluoroethyl)-phosphonic acid |
| PFESA | Perfluoroalkylether sulfonic acid |
| PFEtS | Pefluoroethane sulfonic acid |
| PFHpA | Perfluoroheptanoic acid |
| PFHpDA | Perfluroheptadecanoic acid |
| PFHpS | Perfluoroheptane sulfonic acid |
| PFHxA | Perfluorohexanoic acid |
| PFHxDA | Perfluorohexadecanoic acid |
| PFHxPA | Perfluorohexyl phosphonic acid |
| PFHxS | Perfluorohexane sulfonic acid |
| PFME | Perfluorodimethyl ether; Perfluoromethyl ether; Trifluoro(trifluoromethoxy)methane |
| PFMOBA | Perfluoro-(4-methoxybutanoic) acid |
| PFMOPrA | Perfluoro-2-methoxypropanoic acid |

| Acronym | Explanation |
|---|---|
| PFMPA | Trifluoromethyl-phosphic acid; Perfluoromethyl phosponic acid; (Trifluoromethyl)-phosphonic acid |
| PFMVE | Perfluoromethylvinyl ether |
| PFNA | Perfluorononanoic acid |
| PFO4DA | Perfluoro-3,5,7,9-butaoxadecanoic acid |
| PFO5DoDA | Perfluoro-3,5,7,9,11-pentaoxadodecanoic acid |
| PFOA | Perfluorooctanoic acid |
| PFOcDA | Perfluorooctadecanoic acid |
| PFODA | Perfluorooctadecanoic acid |
| PFOPA | Perfluorooctyl phosphonic acid |
| PFOS | Perfluorooctane sulfonic acid |
| PFOSA | Perfluorooctane sulfonamide |
| PFOSI | Perfluorooctane sulfinic acid |
| PFPA | Perfluoroalkyl phosphonic acid |
| PFPE | Perfluoropolyether |
| PFPeA | Perfluoropentanoic acid |
| PFPeDA | Perfluoropentadecanoic acid |
| PFPeS | Perfluoropentane sulfonic acid |
| PFPiA | Perfluoroalkyl phosphinic acid |
| PFPMIE | Perfluoropolymethylisopropylether |
| PFPPA | Perfluoropentyl-phosphonic acid; (Undecafluoropentyl)phosphonic acid |
| PFPrA | Prefluoropropanoic acid |
| PFPrS | Perfluropropane sulfonic acid |
| PFSA | Perfluoroalkane sulfonic acid |
| PFSIA | Perfluoroalkane sulfinic acid |
| PFSIA | Perfluoroalkane sulfinic acid |
| PFTeDA | Perfluorotetradecanoic acid |
| PFTrDA | Perfluorotridecanoic acid |
| PFUnDA | Perfluoroundecanoic acid |
| PIC | Product of Incomplete Combustion |
| PIGE | Particle-Induced Gamma-ray Emission Spectrometry |
| PIR board | Polyisocyanurate boardstock |
| PM | Particulate Matter |
| pKa | Acid dissociation constant |
| pMDI | Pressured Metered Dose Inhaler |
| PMM | Perfluoro-N-methylmorpholine |
| PMMA | Poly(methyl methacrylate) |
| PMVE | 1,1,2-Trifluoro-2-(trifluoromethoxy)ethene |
| PND | Post-Natal Day |
| PNEC | Predicted No Effect Concentration |
| PolyFAA | Polyfluoroalkyl acid |
| PolyFEAA | Polyfluoroalkylalkylether acid |
| POP | Persistent Organic Pollutant |
| POPRC | POP Review Committee |
| POSF | Perfluorooctane sulfonyl fluoride |
| Pov | Overall environmental persistence |

| **Acronym** | **Explanation** |
|---|---|
| PP | Polypropylene |
| PPA | Polymer Processing Aid |
| PPAR | Peroxisome Proliferator-Activated Receptor |
| ppb | Parts per billion |
| PPE | Personal Protective Equipment |
| ppm | Parts per million |
| PPP | Plant protection product |
| PPPR | Plant Protection Products Regulation |
| PPVE | 1,1,1,2,2,3,3-heptafluoro-3-[(trifluorovinyl)oxy]propane perfluorpropylvinylether |
| PRTR | Pollutant Release and Transfer Register |
| PTF | Polytrimethylene furandicarboxylate |
| PTFE | Polytetrafluoroethylene |
| PU | Polyurethane |
| PV | Photovoltaic |
| PVC | Polyvinylchoride |
| PVDF | Polyvinylidene fluoride |
| PVF | Polyvinylfluoride |
| PXR | Pregnane X-receptor |
| qMS | Quadrupole Mass Spectrometry |
| QSAR | Quantitative Structure-Activity Relationship |
| R&D | Research & Development |
| RAC | Risk Assessment Committee; Committee for Risk Assessment |
| RCF | Root Concentration Factor |
| REACH | Registration, Evaluation and Authorization of Chemicals |
| Repr. | Reproductive toxicity |
| RGP | Rigid Gas Permeable |
| RISE | Research Institute of Sweden |
| RIVM | National Institute for Public Health and Environment; Dutch: Rijksinstituut voor Volksgezondheid en Milieu; The National Institute for Public Health and the Environment NL |
| RMM | Risk Management Measure |
| RMO | Risk Management Option |
| RMOA | Risk Management Option Analysis |
| RO | Restriction Option |
| SAmPAP | Bis(2-{ethyl[(perfluorooctyl)sulfonyl]amino}ethyl) hydrogen phosphate |
| SC | Short-chain, Shorter chain |
| SCF | Shoot-soil Concentration Factor |
| SCFP | Side-chain Fluorinated Polymer |
| SDS | Safety Data Sheet |
| SE | Sweden |
| SEA | Socio-economic Assessment |
| SEAC | Committee for Socio-economic Analysis |
| SEv | Substance Evaluation (under REACH) |
| SFA | Semifluorinated alkane |
| sFTOH | Secondary fluorotelomer alcohol |

| **Acronym** | **Explanation** |
|---|---|
| SHB | Southern Hudson Bay |
| SHF | Shredder Heavy Fraction |
| SLF | Shredder Light Fraction |
| SL-MAC | Secondary Loop Mobile Air Conditioning |
| SME | Small and Medium-sized Enterprises |
| SOD | Superoxide Dismutase |
| SOM | Soil Organic Matter |
| SpERC | Specific Environmental Release Categories |
| SPIN | Substances in Preparations in Nordic Countries |
| SPM | Suspended Particulate Matter |
| SPPS | Solid-phase peptide synthesis |
| SS | Steady State |
| STOT RE | Specific Target Organ Toxicity following Repeated Exposure |
| STP | Sewage Treatment Plant |
| SVHC | Substance of Very High Concern |
| T3 | Triiodothyronine |
| T4 | Thyroxine |
| TA | Trifluoromethanesulfonic acid |
| TAA | Trifluoromethanesulfonic anhydride |
| TBG | Thyroxine-Binding Globuline |
| TC | Total Cholesterol |
| TCE | Trichloroethylene |
| TDAR | T-cell-dependent Antibody Responses |
| TDFA | Trifluoroacetate salt |
| TERC | Toxicology & Environmental Research and Consulting, The Dow Chemical Company |
| Tetraconazole | 1-[2-(2,4-Dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4-triazole |
| *TF* | *Transfer Factor* |
| *TF* | *Total Fluorine* |
| TFA | Trifluoroacetic acid |
| TFAC | Trifluoroacetyl chloride |
| TFAEt | Trifluoroacetic acid ethyl ester |
| TFAH | Trifluoroacetic acid anhydride |
| TFAiP | Trifluoroacetic acid isopropyl ester |
| TFAMe | Trifluoroacetic acid methyl ester |
| TFE | Tetrafluoroethylene |
| TFK | Trifluoroacetone |
| TFMP | 4-(trifluoromethyl)phenol |
| *TFMS* | *Trifluoromethanesulfonic acid, triflic acid* |
| *TfOH* | *Trifluoromethanesulfonic acid, triflic acid* |
| *TFSA* | *Trifluoromethanesulfonic acid, triflic acid* |
| TFSK | Potassium triflinate |
| TG | Triglycerides |
| TH | Tyrosine Hydroxylase |

| **Acronym** | **Explanation** |
|---|---|
| THV | Terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride |
| TMF | Trophic Magnification Factor |
| TNF-ɑ | Tumor Necrosis Factor- ɑ |
| TOC | Total Organic Carbon |
| TOF | Total Organic Fluorine |
| TOP | Total Oxidizable Precursor |
| TOPA | Total Oxidizable Precursor Assay |
| TrFE | Trifluoroethylene |
| TSCA | Toxic Substances Control Act (US) |
| TRR | Total Radioactive Residue |
| TSCF | Transpiration Stream Concentration Factor |
| TSH | Thyroid Stimulating Hormone |
| TTR | Transport Protein Transthyretin |
| TULAC | Textiles, Upholstery, Leather, Apparel and Carpets |
| TV | Television |
| TWI | Tolerable Weekly Intake |
| UBA | German Environment Agency (Umweltbundesamt) |
| UHMW-PE | Ultra High Molecular Weight Polyethylene |
| UK | United Kingdom |
| ULPA | Ultra Low Particulate Air |
| UNECE | United Nations Economic Commission for Europe |
| UNEP | United Nations Environment Programme |
| UNEP Global PFC group | United Nations Environment Programme Global Perfluorinated Chemicals (PFC) Group |
| UNFCCC | United Nations Framework Convention on Climate Change |
| UNU | United Nations University |
| UNR | United Nations Regulation |
| UOF | Unidentified Organic Fluorine |
| UPLC | Ultra Performance Liquid Chromatography |
| URAT | Urate Transporter |
| USA | United States of America |
| US EPA | U.S. Environmental Protection Agency |
| US FDA | United States Food and Drug Administration |
| US NFPA | US National Fire Protection Agency |
| UTV | Unabhängige Tanklagerverband e.V. (German Independent Tank Farm Association) |
| UV | Ultraviolet |
| UWWTD | Urban Wastewater Treatment Directive |
| VDF | Vinylidene fluoride |
| VDI | Verein Deutscher Ingenieure e.V. (Association of german engineers) |
| VF | Vinyl fluoride |
| VOC | Volatile Organic Compound |
| vPvB | Very Persistent and very Bioaccumulative |
| VRF | Variable Refrigerant Flow |
| VTG | Vitellogenin |

| Acronym | Explanation |
|---|---|
| WEEE | Waste of Electrical and Electronic Equipment |
| WFBC | Women Firefighters Biomonitoring Collaborative |
| WFD | Water Framework Directive |
| WFVD | Der Verband Bundesverband Betrieblicher Brandschutz (German Industrial Fire-Fighters Association) |
| WHB | Western Hudson Bay |
| WHO | World Health Organisation |
| WI | Waste Incineration |
| WSR | Waste Shipment Regulation |
| WSTS | World Semiconductor Trade Statistics |
| WtE | Waste-to-Energy |
| ww | Wet Weight |
| WWTP | Wastewater Treatment Plant |
| XPS | Extruded Polystyrene Foam |

# Summary

Per- and polyfluoroalkyl substances (PFASs) are a group of thousands of almost exclusively man-made substances that are used in numerous applications in the EU and EEA. These applications comprise uses in textiles, (food) packaging, lubricants, refrigerants, electronics, construction and many more. The substances are used as substances on their own (either non-polymeric or polymeric) and as constituents in mixtures and (complex) articles for consumer, professional, and industrial uses.

This Annex XV report addresses the risks to the environment and human health of the use of PFASs and provides an assessment of the effectiveness, practicability, monitorability and socio-economic impacts of two restriction options (ROs), i.e. a full ban with a transition period of 18 months (RO1) and a ban with use-specific, mostly time-limited derogations of a duration of 5 or 12 years in addition to a transition period of 18 months (RO2).

Substantiated suggestions for potential alternative regulatory options brought forward during the consultation on the Annex XV report have also been considered by the Dossier Submitters. When these options (as suggested or in an adapted form) have been deemed effective, practical and monitorable and therefore been deemed to constitute a potential valid alternative to the proposed restriction, they are compared to RO1 and RO2 in terms of their proportionality. This refers to options (termed RO3) allowing continued use under strict conditions that minimize emissions over the full life cycle, i.e. regulatory options potentially allowing for adequate control of risks through means other than a ban. In some cases, restriction options with complementary emission reducing measures and requirements attached to use-specific derogations under RO2 have also been considered with a view of improving the effectiveness of the restriction option. Where relevant, such additional restriction options have been assessed in a dedicated section within the sector-/use-specific assessment in Annex E.

Additional restriction options have been assessed for:

- The Manufacture of PFASs
- Transport
- Electronics and semiconductors
- Energy
- Sealing applications
- Machinery applications
- Some technical textiles

Overall, a restriction under REACH is identified as the most suitable risk management option (RMO) to address the identified risks.

Concern

The main concern for all PFASs and/or their degradation products that are in the scope of this restriction proposal is the very high persistence, exceeding the criterion for very persistent (vP) according to Annex XIII of the REACH Regulation by far. PFASs and their degradation products may persist in the environment longer than any other man-made chemical. Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. PFASs enter the environment via emissions during manufacture, the use phase, and the waste stage.

When these substances and their degradation products continue to be released to the environment, the concentration in the environment will increase as mineralization under natural conditions does not take place for the PFASs in the scope of this restriction proposal. Once present in the environment, the removal of PFASs from surface water, groundwater, soil, sediment and biota is technically extremely difficult and very costly, if at all possible. Environmental monitoring of PFASs demonstrates ubiquitous distribution in the environment, including organisms and drinking water sources and food crop, as well as remote and pristine areas making exposure unavoidable and irreversible for now and future generations. Human biomonitoring shows the omnipresence of PFASs in humans, with highly exposed communities showing the highest levels. With the constantly increasing concentrations of PFASs in the environment due to their persistence and ongoing emissions, the exposure of humans and the environment to these substances will inevitably lead to negative effects. Also, exposure to PFASs has a high potential for intergenerational effects. Some scientists argue that the planetary boundaries for PFASs have already been exceeded, and human biomonitoring studies show that the cocktail of PFASs to which parts of the general population are exposed to through different sources (e.g. food, drinking water, products containing PFASs, dust, air) already may result in health risks.

Regulatory risk management options

The irreversibility of the process of a growing environmental stock of PFASs due to emissions from PFAS-containing products during all life cycle stages (manufacture of PFAS, production of products, use phase/service life, and end of life), with associated exposure of humans and the environment, make it necessary to reduce emissions of PFASs to a minimum. Different regulatory risk management options have been considered, e.g. CLH and authorisation, but these options follow a substance-by-substance approach. In contrast, a restriction offers the possibility to define a broad chemical scope, thereby avoiding regrettable substitution of one PFAS by another PFAS (some of which may not have even been engineered yet). At the same time, it allows to tackle the problem of ongoing, uncontrollable emissions at the source, as manufacture and use can be restricted to avoid or minimize emissions. End-of-pipe solutions are not deemed to be achievable, as PFASs are ubiquitously present in a wide range of products intended for industrial, professional and consumer uses. A restriction can cover a wide range of uses and can address the risks arising from the manufacture and use of the substances as such as well as in other substances, in mixtures and in articles, including imported articles from outside the EU. Hence, a restriction is the most appropriate and effective option to adequately control such a large and complex group of substances which are used in numerous applications, whilst also taking into account and mitigating socio-economic impacts of a restriction.

Scope

The chemical scope of the restriction proposal is defined as: Any substance that contains at least one fully fluorinated methyl ($CF_3$-) or methylene (-$CF_2$-) carbon atom (without any H/Cl/Br/I attached to it). There are however a few exceptions (see paragraph below).

It is aligned with the OECD definition[1] of PFASs that was published in 2021, and that has been scrutinized by the international scientific community and is widely accepted. This definition encompasses more than 10 000 PFASs, including a few fully degradable PFAS subgroups. As these fully degradable subgroups, which can be described by their key structural elements, do not fulfil the underlying concern of high persistence (see above), they are excluded from the scope of this restriction proposal.

As outlined above, the restriction proposal is tailored to address the manufacture, placing on the market, as well as the use of PFASs as such and as constituents in other substances, in mixtures and in articles above a certain concentration. All uses of PFASs are covered by this restriction proposal, regardless of whether they have been specifically assessed by the Dossier Submitters and/or are mentioned in this report or not, unless a specific derogation has been formulated. However, this restriction proposal does not cover the use of PFASs in fire-fighting foams (Aqueous Film Forming Foams; AFFFs), which is assessed in a separate restriction proposal. Both proposals are complementary to each other. Additionally, this restriction is not

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[1] Any substance that contains at least one fully fluorinated methyl ($CF_3$-) or methylene (-$CF_2$-) carbon atom (without any H/Cl/Br/I attached to it).

meant to affect any other restrictions already included in Annex XVII or prohibitions in other applicable Union legislation (e.g. in the POP Regulation).

Socio-economic impacts and proportionality

The Dossier Submitters have identified the PFAS uses in which the largest amounts of PFASs are used and emitted. This has been done through literature research, stakeholder consultations, and a call for evidence. The 2023 consultation on the Annex XV restriction dossier resulted in over 5 600 comments from stakeholders, a large part also relating to socio-economic impacts. Information from these comments has been used to update the dossier, and also resulted in the inclusion of eight additional applications/use sectors.

Twenty-two applications/uses – subdivided in numerous sub-uses - have been addressed in detail in this report. For the EEA, this resulted in an estimated amount of 186 000 to 340 000 t of PFASs introduced to the market in 2020, which – due to the expected economic growth in relation to several applications – is expected to increase further under the baseline scenario. Over a 30-year period (2025 – 2055) the expected mean PFAS tonnage used in the EEA is 27 million tonnes, leading to emissions of about 4.7 million tonnes during the manufacture of products containing PFAS, the use phase and the end-of-life phase when no action is taken.

The benefits of a restriction are, amongst others, the avoided negative human health effects associated with the continued use of PFASs. The magnitude of the impact of continued use of PFASs on human health cannot be quantified but current combined exposure to some regulated PFASs already exceeds existing limit values. Therefore, due to structural similarities and a similar hazard profile, (co-)exposure to other, non-regulated, PFASs should be minimized. This implies that restriction option RO1 (being a full ban with an 18 month transition period), that reduces the increase of the environmental pollution burden of PFASs the most, compared to the baseline scenario, will result in the highest benefit to society in terms of avoided long-term human health impacts resulting from exposure to PFASs.The socio-economic costs of PFAS emissions to the environment are considerable and are growing with prolonged PFAS use. Complete monetarization of the benefits of a restriction is however not possible, e.g. due the inability to quantify human health impacts. As it is concluded that PFASs should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances, emissions are used as a proxy for risk in line with the standard approach for PBT/vPvB substances. A cost-effectiveness analysis is the standard approach for assessing proportionality of regulatory options for such substances. In most cases, quantification of costs was not possible, e.g. due to data gaps in relation to various relevant elements and challenges with respect to the representativeness of available data. In most cases, the costs of the restriction options have therefore been analysed in qualitative terms. Costs at use group level are graded on a 5-level scale ranging from very low to very high and compared to the level of effectiveness, also graded on a 5-level scale to conclude on proportionality. Details on the expected costs and emission reduction for the 22 uses and associated proportionalty of restriction options are provided in section 2.4.

Overall, a restriction with use-specifc derogations (RO2) is deemed to reduce emissions by 83%. In comparison, a full ban is deemed to reduce emissions by around 96%. Costs under RO2 are generally found to be lower than under RO1, rendering RO2 an option that is preferable over RO1. Where analysed, RO3s are deemed to be proportionate for electronics and semiconductors, likely proportionate for energy, manufacturing and technical textiles and not sufficiently effective for transport, sealing applications and machinery applications.

All restriction options, RO1, RO2 and RO3, are considered sufficiently enforceable. RO1 is likely not implementable, and therefore also not manageable, while RO2 and RO3 are evaluated as implementable and manageable by the Dossier Submitter. Hence, RO2 and RO3 are concluded to be practical with regards to implementability, enforceability and manageability.

**Proposed restriction - Annex XVII entry PFASs (Restriction Option 2)**

| **Column 1**<br><br>Designation of the substance, of the group of substances or of the mixture | **Column 2**<br><br>Conditions of restriction |
|---|---|
| Per- and polyfluoroalkyl substances (PFASs) defined as:<br><br>Any substance that contains at least one fully fluorinated methyl ($CF_3$-) or methylene (-$CF_2$-) carbon atom (without any H/Cl/Br/I attached to it).<br><br>A substance that only contains the following structural elements is excluded from the scope of the restriction:<br><br>$CF_3$-X or X-$CF_2$-X’,<br><br>where X = -OR or -NRR’ and<br>X’ = methyl (-$CH_3$), methylene (-$CH_2$-), an aromatic group, a carbonyl group (-C(O)-), -OR’’, -SR’’ or –NR’’R’’’;<br><br>and where R/R’/R’’/R’’’ is a hydrogen (-H), methyl (-$CH_3$), methylene (-$CH_2$-), an aromatic group or a carbonyl group (-C(O)-). | 1. Shall not be manufactured, used or placed on the market as substances on their own;<br><br>2. Shall not be placed on the market in:<br>a. another substance, as a constituent;<br>b. a mixture,<br>c. an article<br><br>in a concentration of or above:<br>i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)<br>ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors<br>iii. 50 ppm for total PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.<br><br>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.<br><br>4. By way of derogation, paragraphs 1 and 2 shall not apply to<br>a. active substances in biocidal products within the scope of Regulation (EU) 528/2012<br>b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009<br>c. active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC<br>d. placing on the market of articles which were already in end-use in the Union<br>e. spare parts intended to replace PFAS-containing articles in articles or complex objects until 20 years after the last date when the complex article was allowed to be placed on the market for the first time or until the end of service life for the specific object, when it is shorter than 20 years<br>f. spare parts used in articles or complex objects for which legal obligations related to the use of specific spare parts exist until the end of service life of the complex object<br>g. starting materials and intermediates in the manufacture of PFASs for a use listed under paragraphs 4, 5 or 6<br>h. production of PFAS containing mixtures or articles in the upstream supply chain for a use listed under paragraphs 4, 5 or 6 |

| **Column 1**<br>Designation of the substance, of the group of substances or of the mixture | **Column 2**<br>Conditions of restriction |
|---|---|
|  | i. uses under product and process orientated research and development (PPORD; art. 67(1) of EU-REACH)<br>j. paper and board articles containing recovered material, with the exception of food-contact material and packaging<br>k. textile articles containing recovered material, with the exception of toys as defined in Directive 2009/48/EC, until 13.5 years after EiF<br>l. plastic articles containing recovered material, with the exception of food-contact material and food-contact packaging and toys as defined in Directive 2009/48/EC, until 23.5 years after EiF<br>m. production of PFAS with or without the use of fluorinated polymerisation aids in the production of polymeric PFAS under controlled conditions with average emission factors (= Annual emission of PFAS / total annual amount of PFAS manufactured on site) not exceeding<br>i. 0.0090% to air, 0.0010% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing until end of 2030;<br>ii. 0.0030% to air, 0.0006% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing from end of 2030 onwards;<br>iii. 0.01% to all compartments for all PFAS emissions not mentioned above from sites manufacturing polymeric and non-polymeric PFAS 6.5 years after EiF.<br><br>Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information:<br>i. the derogation that the intended use belongs to;<br>ii. the identity and quantity of the active substance placed on the market<br>The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii)<br><br>Suppliers of paper and board articles referred to in point j) containing recovered paper and board, suppliers of textile articles referred to in point k) containing recovered material and suppliers of plastic articles referred to in point l) containing recovered material shall submit to national enforcement authorities upon request documentary evidence to substantiate the claims on the recovered origin of paper and board, textiles and plastic in those articles. Claims made on the recovered origin of paper and board, textiles and plastic in imported articles shall be accompanied by a certificate that provides proof of traceability and recycled content, issued by an independent third party. |

| **Column 1**<br>Designation of the substance, of the group of substances or of the mixture | **Column 2**<br>Conditions of restriction |
|---|---|
| | Suppliers of plastic articles or complex objects falling under the scope of the WEEE Directive (Directive 2021/19/EU) or ELV Directive (Directive 2000/53/EC) as well as suppliers of PVC articles listed in paragraph 18 (a to f) of Regulation (EU) 2023/923 on lead and its compounds in PVC containing intentionally added PFASs in concentrations of or above the limits set out in Paragraph 2 shall ensure, before placing those articles on the market, that they are visibly, legibly and indelibly marked with the statement: "Contains intentionally added PFASs". Where the marking cannot be provided on the article due to the nature of the article, it shall be on the packaging of the article.<br>5. By way of derogation, paragraphs 1 and 2 shall not apply to:<br>a. personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, until 13.5 years after EiF;<br>b. personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers, until 13.5 years after EiF;<br>c. impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EiF;<br>d. hard chrome plating until 6.5 years after EiF;<br>e. refrigerants in low temperature refrigeration below -50 °C until 6.5 years after EiF;<br>f. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF;<br>g. refrigerants in refrigerated centrifuges until 13.5 years after EiF;<br>h. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;<br>i. foam blowing agents in thermal insulation foam until 13.5 years after EiF;<br>j. propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF. The derogation does not apply to products intended for entertainment and decorative purposes for the general public;<br>k. fluorinated gases used as clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EiF;<br>l. preservation of cultural paper-based materials until 13.5 years after EiF;<br>m. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EiF<br>n. refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear |

| **Column 1**<br>Designation of the substance, of the group of substances or of the mixture | **Column 2**<br>Conditions of restriction |
|---|---|
| | equipment put on the market before 18 months (or placed on the market after 18 months after EiF based on an applicable derogation);<br>o. [potential derogation for use of fluorinated gases at the CERN research installation unit until 13.5 years after EiF].<br>p. additives to hydraulic fluids in transport vehicles until 13.5 years after EiF;<br>q. refrigerants in mobile air conditioning-systems and heat pump systems in i) light duty electrical vehicles until 6.5 years after EiF; ii) all other vehicles until 13.5 years after EiF<br>r. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF;<br>s. coatings and films on displays and lenses of electronic complex objects for 6.5 years after EiF;<br>t. printed circuit boards and antennas for 13.5 years after EiF<br>u. photonics for 13.5 years after EiF;<br>v. heat transfer fluids for 2-phase immersion cooling for 13.5 years after EiF;<br>w. semiconductor manufacturing until 13.5 year after EiF;<br>x. coatings and films of electronic components (excluding displays and lenses) for 13.5 years after EiF;<br>y. binders and electrolytes in batteries until 13.5 years after EIF<br>z. polymer additives used for fire safety purposes in construction products until 13.5 years after EiF;<br>aa. industrial and professional uses of lubricants or lubricant additives until 13.5 years after EIF;<br>bb. gas and oil tracers until 13.5 years after EiF;<br>cc. toners until 13.5 years after EiF;<br>dd. latex printing inks until 13.5 years after EiF;<br>ee. electrophotographic press units until 13.5 years after EiF;<br>ff. kinetic printing components until 13.5 years after EiF;<br>gg. photosensitive materials until 13.5 years after EiF<br>hh. toners for use in existing equipment put on the market until 13.5 years after EiF;<br>ii. latex printing inks for use in existing equipment put on the market until 13.5 years after EiF;<br>jj. excipients in medicinal products for ophthalmic and dermatological therapies until 13.5 years after EiF<br>kk. propellants in pMDIs until 6.5 years after EiF<br>ll. military applications until 13.5 years after EiF<br>mm. HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases |

| **Column 1**<br>Designation of the substance, of the group of substances or of the mixture | **Column 2**<br>Conditions of restriction |
|---|---|
|  | for 13.5 years after EiF, excluding general (HVAC) ventilation;<br>nn. sound-permeable and vent filters for electrical and electronic equipment for 6.5 years after EiF;<br>oo. oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries for 13.5 years after EiF;<br>pp. industrial use as media in liquid-liquid separation for 13.5 years after EiF;<br>qq. technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection until 13.5 years after EiF;<br>rr. technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay until 6.5 years after EiF;<br>ss. woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795 for 13.5 years;<br>tt. impregnation agents for re-impregnation of articles referred to in paragraph 5tt until 13.5 years after EiF;<br>uu. ionic liquids used in industrial uses until 6.5 years after EiF;<br>vv. solvents used in industrial uses until 13.5 years after EiF;<br>ww. catalysts and processing aids used in industrial uses until 13.5 years after EiF.<br>6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in:<br>a. polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) until 6.5 years after EiF.<br>b. non-stick coatings in industrial bakeware until 6.5 years after EiF;<br>c. implantable medical devices (including medical implants and meshes) until 13.5 years after EiF;<br>d. invasive medical devices (e.g. tubes and catheters) until 13.5 years after EiF;<br>e. packaging for medical devices until 13.5 years after EIF;<br>f. i) vehicle systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles*)] that are subject to EU vehicle type approval, where the type approval was obtained within 13.5 years after EiF (e.g., motor vehicles within the |

| **Column 1**<br>Designation of the substance, of the group of substances or of the mixture | **Column 2**<br>Conditions of restriction |
|---|---|
| | scope of Regulation (EU) 2018/858, (EU) 2019/2144 or Directive 2007/46/EC, agricultural and forestry vehicles with the scope of Regulation (EU) 167/2013, aircraft within the scope of Regulation (EU) 2018/1139 or (EU) 748/2012, watercraft within the scope of Directive 2013/53/EU or 2009/45/EC, and rail vehicles within the scope of Regulation (EU) 2016/797 or Directive (EU) 2016/798); OR<br>ii) systems, components or separate technical units [(excluding ‘sealing applications’, batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles*)] in vehicles that are not within the scope of paragraph a, where the use of fluoropolymers or perfluoropolyethers are strictly necessary for safety or environmental performance of those vehicles until 13.5 years after EiF. e.g., braking, restraint, lighting/signalling, driver assistance systems, emission control.<br>g. heat transfer fluids for industrial and professional use of vapor phase soldering for electronics for 13.5 years after EiF;<br>h. wires and cables (incl. connectors) for 13.5 years after EiF<br>i. insulation material of electronic components (excluding wires, cables and connectors) for 13.5 years after EiF;<br>j. anti-drip agent in plastics of electronic components for 13.5 years after EiF;<br>k. fuel cells and electrolysers until 13.5 years after EiF;<br>l. separator coatings for batteries until 6.5 years after EIF<br>m. PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers until 6.5 years after EIF<br>n. front- and backsheets in photovoltaic cells until 6.5 years after EIF<br>o. bridge and building bearings until 13.5 years after EiF;<br>p. sealing applications in industrial uses until 13.5 years after EiF<br>q. machinery applications in industrial uses until 13.5 years after EIF<br>r. coatings in release liners and backing film in transdermal patches until 13.5 years after EiF<br>s. blisters for solid oral dose formulations until 6.5 years after EiF |

| **Column 1**<br>Designation of the substance, of the group of substances or of the mixture | **Column 2**<br>Conditions of restriction |
|---|---|
| | t. coated rubber stoppers in vials/flasks for injectable medicinal products until 13.5 years after EiF<br>u. coated canisters in pressurized metered-dose inhalers (pMDIs) until 13.5 years after EiF;<br>v. coated plungers in pre-filled syringes until 13.5 years after EiF<br>w. pre-filled injection pens & autoinjectors until 13.5 years after EiF<br>x. explosives in military applications until 13.5 years after EiF<br>y. industrial use of fluoropolymers in filtration and separation media for water treatment and purification for 6.5 years after EiF.<br>7. Manufacturers, importers of PFASs or PFAS containing articles as well as downstream users formulating PFAS-containing mixtures making use of any of the derogations according to paragraphs 5 a)-c), e) – r), t) - jj), ll) - mm), oo) – qq), ss) – tt), vv)-ww), and 6c) – k), o) – r), t) – x), shall from (EiF + 18 months) provide by 31 May of each calendar year a report to the Agency containing:<br>i. the derogation that the intended use belongs to;<br>ii. the identity and quantity of the substances placed on the market in the previous year.<br>The Agency shall make the information available to the Commission and Member States by 31st August every year;<br>8. Without prejudice to paragraph 7, manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any of the derogations in paragraphs 5 or 6 shall establish a site-specific management plan which shall include:<br>i. information on the identity of the substances and the products they are used in<br>ii. a justification for the use;<br>iii. details on the conditions of use and safe disposal.<br>The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request.<br>9. This restriction does not affect existing entries of REACH regulation Annex XVII, apart from entries 28 to 30, as well as substances listed in Regulation 2019/1021 (POP-Regulation). Other Union legislation addressing substances within the scope of this restriction shall be adhered to notwithstanding this restriction. |

## Explanatory notes

General

The Dossier Submitters assessed the appropriateness of various restriction options, including a restriction option that comprised a full ban on PFASs (RO1), a ban on PFASs with use-specific transitional periods (RO2s) as well as 'additional restriction options' for certain uses that comprised other measures to address the identified risk (RO3s). Additional restriction options (RO3s) were developed based on the comments received in the consultation on the Annex XV report and their assessment is reported within the sector assessments in Annex E. Whilst the Dossier Submitters propose RO2 (ban with use-specific transitional periods) for the draft Annex XVII entry text (above), the appropriateness of all assessed restriction options should be evaluated by RAC and SEAC and considered by decision-makers.

According to REACH Article 67, restrictions do not apply to manufacture, placing on the market or use of a substance in scientific research and development (SR&D). Scientific research and development means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year. In ECHA's guidance[2] it is explained that examples of SR&D may include any experimental research or analytical activities at a laboratory scale such as synthesis and testing of applications of chemicals, release tests, etc. as well as the use of the substance in monitoring and routine quality control or in vitro diagnostics at a laboratory scale under controlled conditions.

Column 1 – Substance identity

PFASs form a broad group of substances that include inter alia non-polymeric PFASs like perfluoroalkyl carboxylic acids, perfluorocarbons, perfluoroalkane sulfonic acids and trifluoromethyl substituted substances as well as polymeric PFASs like fluoropolymers, perfluoropolyethers and side-chain fluorinated polymers. All PFASs subject to this restriction proposal are either persistent themselves or degrade to persistent PFASs, except for a few specific PFAS subgroups with combinations of key structural elements for which it can be expected that they will ultimately mineralize in the environment. As these specific PFAS subgroups do not form ultimately persistent PFAS arrowheads, they are excluded from the scope definition of this restriction proposal. In section 1.1.1, the substance identity and scope are further explained and justified.

Column 2 - Conditions

Paragraph 1:

This paragraph addresses PFASs as such and, in paragraph 2 also covers their placing on the market as constituents in other substances

Paragraph 2:

This paragraph is listed separately and only covers placing on the market to allow the continued use of PFAS containing substances, PFAS mixtures and articles already on the market. The paragraph does not ban the manufacture of substances which have PFAS as constituents, since there is no reason for manufacturing, if placing on the market is forbidden. In addition, this paragraph sets the concentration limits above which the placing on the market of PFASs in other substances, in mixtures or in articles shall be restricted. Three different concentration limits are proposed.

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[2] ECHA Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)

The first two values (25 ppb for individual PFASs and 250 ppb for the sum of PFASs) refer to a targeted analysis of PFASs contained in another substance, mixture or article, i.e. the measurement of PFASs with an available analytical method for a specific set of substances and quantified against reference standards. Such methods do not apply to polymeric PFAS (see section E.4.1.4) and they are therefore not included in the quantification. The term 'polymeric PFAS' is explained in section 1.1.1 and Figure 1. The concentration limit for the sum of PFASs (250 ppb) may be calculated from targeted PFAS analysis either analysed directly as sample or after chemical degradation of the sample material. Again, such analytical methods do not apply to polymeric PFAS. However, methods like TOPA with a preceding chemical degradation step may include degradation products from e.g. side-chain fluorinated polymers which are measured in targeted PFAS analyses and included in the analysis.

The third value (50 ppm) is broader and addresses PFAS beyond the available analytical reference standards, including fluoropolymers. In this case, a total fluorine content analysis is used to demonstrate the presence of organic fluorine. As the measured value will also include potential fluorine from sources other than PFASs, it is necessary to differentiate between PFAS and non-PFAS. Hence, if total fluorine exceeds 50 mg F/kg during enforcement analysis, proof for the fluorine measured being part of either PFASs or non-PFASs should be provided to the authorities. The proof could be either supply chain information or based on analysis. The information put forward should be compared with the 50 ppm limit value.

Currently, there are analytical methods under development that can act as an alternative to the information requirement proposed above for the differentiation between PFAS and non-PFAS. Methods like pyrolysis GC/MS and $^{19}$F NMR can confirm the presence of $CF_2$ and $CF_3$ units in the chemical structure of substances, and therefore, also confirm the PFAS nature of the substances, see section2.5.5. However, currently the LOQ for pyrolysis GC/MS tends to be higher than the LOQ for CIC, which means that more development is needed until all of the fluorine content detected with CIC can be confirmed as $CF_2$ or $CF_3$. In addition, it is so far unclear whether the method can separate out substances with $CF_2$ or $CF_3$ units linked to H, Cl, Br or I, which may be out of scope.

A systematic workflow for compliance testing for the universal restriction proposal, based on a recent scientific paper, has been explained in section 2.5.5 Sampling strategy and approach to enforcement.

The relationship between mg F/kg sample material and mg PFASs/kg depends on the percentage of F in the molecular structure of PFASs in the sample. How to calculate this transformation is explained in Annex E.4. In the case of e.g. PFOS, 50 mg F/kg corresponds to 77.4 mg PFOS/kg (PFOS consists of 64.6% F).

All three concentration limits apply to any product, and a product should not contain PFAS over any of the indicated concentration limits unless the product is covered by any of the specific derogations listed in the draft entry text.

Paragraphs 4-6:

Proposed derogations in paragraphs 4 to 6 intend to always cover any substance of the synthesis pathway necessary to manufacture the final substance (e.g. the active substance in a plant protection product or a fluoropolymer). Section 2.2.3 details what is covered for active substances specifically. This does, however, not extend to PFAS-based solvents, and processing chemicals needed for manufacture, unless these are explicitly mentioned in those paragraphs.

Paragraph 4d:

The derogation relates to the placing on the market of secondhand articles. The placing on the market of other articles that have already been placed on the market is not covered by this derogation, e.g. stocks of intermediate and finished products. The purpose of the derogation is to extend the service-life of articles already manufactured and to address the problem that sellers of second-hand articles and enforcement authorities often do not know whether articles contain PFAS. The reflections for this derogation are presented in Annex E.3.2.

Paragraph 4e-f):

The derogations relate to the placing on the market of spare parts, i.e. articles and complex objects intended for the maintenance and repair of another article or complex object. The duration of derogation 4e is 20 years after the transition period for an article or complex object that is maintained or repaired has ended, i.e. 18 months, 6.5 years or 13.5 years after entry into force plus 20 years (or until the end of service life for the specific object). In addition, an indefinite derogation 4f (until the end of service life for the specific object) is proposed for uses that have legislation/certification related to the use of spare parts. The purpose of the derogation is to extend the service-life of articles already manufactured when there are no technically or economically feasible PFAS-free spare parts available. The reflections for this derogation are presented in Annex E.3.3.

Paragraph 4j):

The derogation relates to the placing on the market of articles made of recovered paper and board, which might contain PFAS above the specified concentration limits due to contamination resulting from the intentional use of PFAS in paper and board articles ending up in waste streams. The analysis underlying this derogation is presented in Annex E.3.4.3.

Paragraph 4k):

The derogation relates to the placing on the market of articles made of recovered textiles, which might contain PFAS above the specified concentration limits due to contamination resulting from the intentional use of PFAS in textile articles ending up in waste streams. The analysis underlying this derogation is presented in Annex E.3.4.4. The derogation solely covers the recycling of non-PFAS materials commonly used for fibres, e.g. polyester and cotton, and not the recycling of fluoropolymers.

In accordance with Commission Regulation (EU) 2016/26 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards nonylphenol ethoxylates, 'textile article' means any unfinished, semi-finished or finished product which is composed of at least 80% textile fibres by weight, or any other product that contains a part which is composed of at least 80% textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels.

Paragraph 4l):

The derogation relates to the placing on the market of articles made of recovered plastic, which might contain PFAS above the specified concentration limits due to contamination resulting from the intentional use of PFAS in plastic articles ending up in waste streams. The analysis underlying this derogation is presented in Annex E.3.4.2. The derogation solely covers the recycling of non-PFAS materials commonly used for plastic articles, e.g. PP, PE and PET, and not the recycling of fluoropolymers.

Paragraph 4m):

The derogation relates to the manufacturing of all PFAS that are intended to be used for derogated uses or are intended to be sold to third (non-EEA) countries. Emission limits are proposed to ensure the minimisation of emissions according to current best practices. Fluoropolymer manufacturers in the EEA already announced to implement measures stipulated under i. and ii. voluntarily. Therefore, no transition period is required for i. and the transition period for ii. is the same as announced by the manufacturers. It is expected that necessary adjustments to the production processes for iii. can be implemented within 6.5 years. iii. applies to all PFAS manufacturing, including manufacturing of fluoropolymers because i. and ii. only address emissions resulting from the polymerisation aid technology used in manufacturing of fluoropolymers. It is the Dossier Submitters' understanding that i. and ii. do not address all emissions resulting from the manufacturing of fluoropolymers, e.g., emissions of solvents, monomers, other by-products, and fluoropolymers themselves.

The proposed emission limit values are intended to apply without prejudice to other (stricter) permits and obligations in relation to emissions issued under EU or national legislation, e.g. under the Industrial Emissions Directive.

The derogation is non-time limited based on the fact that the manufacturing/production of PFAS has the sole purpose of producing PFASs. Accordingly, analysis of alternatives for PFASs manufacture as such has no meaning, as manufacturing has no independent function. Consequently, alternatives cannot become available over time, i.e. a time-limited derogation would inevitably result in closure of all manufacturing facilities in the EEA.

As all PFAS emissions are intended to be reduced in the manufacturing of PFAS, a differentiation between emissions of fluorinated processing aids and other PFAS emissions from manufacturing sites was not deemed necessary.

Paragraph 5:

For the uses listed in this paragraph, derogations from paragraphs 1 and 2 are proposed.

Some derogations in this paragraph refer to typical uses of fluorinated gases, some of which are also regulated in the F-gas Regulation (Regulation (EU) 517/2014). The F-gas Regulation does not per se restrict the use of the substances but rather aims for a reduction of their use. In addition, there are other fluorinated gases fulfilling the PFAS definition in column 1 which can be used for the same purpose. Therefore, these substances should be in the scope of this restriction proposal. Nevertheless, for some key applications of fluorinated gases alternatives are not yet available. In order to ensure the availability of these commercially relevant applications, specific derogations are proposed by the Dossier Submitters.

In some derogations, reference is made to industrial and/or professional uses. These terms are not defined under REACH. However, the ECHA Guidance on Information Requirements and Chemical Safety Assessment in its chapter R.12 on use description recommends understanding the concept of "professional use" as means to distinguish between use at industrial sites and uses outside industrial sites, but not by consumers or the general public. Uses at industrial sites usually are considered better controlled and less widespread in contrast to uses by professionals.

In the following, some specific derogations of paragraph are further outlined:

5a-b) Personal protective equipment (PPE) specified in Regulation (EU) 2016/425, is equipment worn to minimize exposure to hazards that cause serious injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other hazards.

PPE covers a wide range of products such as safety helmets, gloves, eye protection, hazmat suits, high-visibility clothing, safety footwear, safety harnesses, ear plugs, ear defenders and respiratory protective equipment (RPE) and protective clothing.

5e) Temperatures below -50 °C are needed in different kinds of industrial applications and are currently difficult to reach without the use of fluorinated refrigerants. Industrial processes with such needs may include inter alia certain mining applications and processing.

5g) The use of refrigerated centrifuges represents a specific application where the centrifuge rotor is placed in a refrigerated space for precise temperature control. The availability of non-PFAS alternatives that fulfill the requirements of this application is limited. In such systems, a rotor failure would risk a ruptured refrigerant system and the use of flammable refrigerants or high-pressure systems would represent a hazard to the area. Refrigerated centrifuges should be designed with hermetically sealed systems to avoid leakage, and at end of life, the fluorinated gas should normally be collected under controlled circumstances to avoid releases.

5h) The derogation for refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives is included to make sure that such equipment is available where non-PFAS alternatives are restricted at the national level according to standards and building codes due to properties like e.g. flammability. Such standards and codes are reviewed at regular intervals (e.g. every 4th year) and updated according to technical development. The development in HVACR equipment gradually makes refrigerant loadings lower and equipment safer and it is expected that the standards and codes over time are allowing more use of PFAS-free refrigerants. 5m) The derogation applies to fire-suppressing agents in the form of fluorinated gases used for extinguishing fires in high-risk situations where alternatives pose significant risk to health or the assets to be protected. These situations may include aviation, data centres and cultural/historic resources. Such agents are different from fire-fighting foams which are aqueous mixtures. The Dossier Submitters note that the Montreal Protocol Technology and Economic Assessment Panel (TEAP) has expressed concern that the proposed restriction of fluorinated gases for fire-suppression, despite the 13.5 year transitional period proposed, could result in unintended negative impacts by undermining efforts to phase out the use of halons (ozone-depleting substances) and high-GWP HFCs as fire suppressants via the Montreal Protocol. This is because low-GWP fluorinated gases (within the scope of the restriction) are expected to remain the only alternatives for several fire suppression applications over the medium to long term, see Annex E.

5i) The derogation related to foam blowing agents in thermal insulation foam applies to different kinds of foam used for insulating purposes, including spray foam, foam boards, flexible foam etc. The background for the derogation is the low flammability and low heat transfer potential of the relevant fluorinated gases which make them efficient and suitable in building insulation. Although non-PFAS alternatives are available for some applications, some time is still required until alternative foam blowing agents can replace fluorinated gases fully. This sub-use and derogation is not related to fire-fighting foam, which is a different use and is covered in a separate restriction proposal[3]. The Dossier Submitters note that Annex IV of the F-gas regulation envisages a phase out for all fluorinated greenhouse gases in 'foams' by 1 Jan 2033, except if required for safety standards. Alignment of phase out periods between these two pieces of legislation may be considered.

5j) Many spray applications rely on a propellant that continuously delivers a homogenous and uniform aerosol until the container is empty. This often requires a liquified propellant rather

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[3] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6, date of access: 2024-07-03.

than a high-pressure gas. At the same time low flammability is required for many applications. Derogation is not granted for products that are intended for entertainment and decorative purposes for the general public.

5l) The derogation covers the preservation of cultural paper-based materials which rely on a solvent which does not dissolve ink or destroy paper. In the procedure an alkaline treatment neutralizes the acid present in the paper which destroys the material over time.

5m) For switchgear operated at voltages up to 145 kV non-PFAS solution are available an in operation today. However, for high-voltage systems some time is still needed for development of alternatives to the current fluorinated gases used as insulating gases.

5n) This derogation covers the refilling and maintenance of equipment with fluorinated gases to allow for continued functioning as long as the equipment was already in use when the restriction entered into force, or equipment has been put in operation within any of the relevant derogations. Equipment includes HVACR, fire-suppressing and switchgear equipment, for which a certain level of fluorinated gases are needed for the functioning. Examples include industrial, transport or commercial refrigeration, mobile air conditioning (MAC), stationary air conditioning, heat pumps (including high-temperature), large industrial systems, Organic Rankin Cycle and district heating/cooling, as well as fire-suppressing systems in e.g. airplanes, IT hardware or museums. The best option for the environment with such equipment is considered to be that the equipment is used until the end of its service life as manufacture of alternative equipment also has a considerable environmental cost. This will avoid premature termination of equipment and the need for replacement with new equipment. However, use of non-PFAS alternatives is encouraged where equipment allows the use of such drop-in alternatives.

5o) A potential derogation for reconsideration is included for the use of fluorinated gases at the CERN research installation. The installation uses high volumes of fluorinated gases for cooling and in detectors and has large emissions. However, the Dossier Submitters are not able to conclude on the proportionality of this potential derogation.

5p) The derogation relates to uses of PFASs as anti-erosion and anti-corrosion additives in hydraulic systems in transport vehicles.

5q) The derogation relates to mobile air conditioning and heat pumps for heating and cooling and is differentiating between light duty electrical vehicles, which have come farther in the development of air-conditioning and heating/cooling based on non-PFAS refrigerants, and other vehicles. Light-duty vehicles are to be understood as passenger cars and vans of vehicle category M and N[4]. Hybrid vehicles are grouped together with combustion engine vehicles as they will need to rely on similar technical solutions (i.e. other vehicles). The duration of the proposed transitional period reflects that alternative, non-PFAS, refrigerants will have been implemented in these vehicle classes by some but not all vehicle manufactures at the entry into force of the restriction. The derogation covers placing on the market of vehicles containing refrigerants, as well as refilling of air-conditioning or heat pump systems during service. 'Other vehicles' in this context is intended to include trucks, buses, motor and touring caravans, non-road vehicles, trains, ships, airplanes and spacecrafts etc.

5r) Reefer containers used in marine transportation may be operated by non-PFAS refrigerants. There are numerous examples of such systems. However, for other types of

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[4] https://single-market-economy.ec.europa.eu/sectors/automotive-industry/vehicle-categories_en, date of access: 2024-07-03.

transport refrigeration, a need for fluorinated refrigerants due to safety reasons until alternatives are available has been justified.

5s) The derogation covers PFAS used for coating and films on display and lenses in electronic complex objects. Complex objects are objects that contain several smaller articles such as phones and computers, where PFAS can be used as e.g. abrasion resistance, anti-reflective or anti-smudge.

5t) The derogation covers PFAS used for printed circuit boards (PCB) and antennas. The derogations covers all uses of PCB's and antennas, such as the use in aerospace, defense or communication.

5u) The derogation covers the use of photonics. Photonics relates to generation, control, manipulation, and detection of light. This use covers, LCD, OLED, optical fibres (polymer optical fibres) and other optical uses excluding uses covered by derogation 5t.

5v) The derogation covers the use of PFAS as a heat transfer fluid in 2-phase immersion cooling and does therefore not apply to other heat transfer fluid applications such as 1-phase immersion cooling or cold plate cooling. The derogation relates to the use of PFAS that change from a liquid state to a gaseous state in order to remove heat from electronic components. These fluids can be used in datacenters or in thermal management systems in vehicles.

5w) The derogation covers PFAS used for semiconductor manufacturing processes. As several other applications such as MEMS also apply similar technolgies, these uses are considered covered by this derogation. The derogation does not cover filters, chillers, seals and other machinery equipment as they are considered part of other sector assessments such as 'sealing applications', 'technical textiles', 'application of fluorinated gases' and 'machinery'. An exception is the use of pellicle membranes and wafer processing and transportation equipment.

5x) The derogation covers PFAS used for coating and films of electronic components excluding uses covered by derogation 5t. This derogation includes coatings on PCB's, sensors and several uses of medical imaging.

5y) The derogation covers binders and electrolytes in all batteries. Other PFAS uses in batteries are covered under derogation 6j and in the sealing application or technical textiles sector.

5z) The derogation of polymer additives used for fire safety purposes relates to additives such as PTFE or PFBS which can be added to non-PFAS plastics such as polycarbonate for anti-dripping, flame retardant and anti-static properties in order to prevent the occurrence of fires or to limit the flammability of the material. The derogation covers the use of these additives in plastics for construction products as defined based on sub-uses in Annex A.3.14.1.2.

5aa) The derogation relates to industrial or professional uses of lubricants or lubricant additives. The derogation is intended for operations and equipment that require performance under harsh conditions (very high or low temperatures, very high or low pressure, chemical resistance, resistance to radiation etc.). However, since these conditions cannot be reliably defined the derogation applies to industrial and professional uses generally, where it is assumed that uses correspond to 'harsh conditions'. Consumer uses are not derogated.

5bb) The derogation for the use of PFAS as gas or oil tracers relates to the use of tracers in gas and oil production, as well as in carbon capture and storage and geothermal energy applications, for mapping of geological formations and wells. Typical tracers covered include various perfluoroalkanes as described in section A.3.16. The derogation does not cover water tracers as it is considered that alternatives are available for this application.

5hh+ii) These derogations cover the use of toners and latex printing inks in equipment that has been purchased within the 12-year derogation period (13.5 years with the default transition period of 18 months). This period allows sufficient time for developing, certifying and distributing alternative toners, latex printing inks and printing equipment that is compatible with those new toners and inks. The purpose of these derogations is to avoid early redundancy of existing printing equipment that cannot use alternative consumables, thus minimising waste and environmental impact. As printing equipment put on the market after 13.5 years after EiF would be adapted to the new (PFAS-free) generation of toners and inks rather than PFAS-based consumables, demand for PFAS-based consumables in new equipment is expected to be eliminated.

5jj) The derogation covers fluorinated gases as propellants in pMDIs. The F-gas regulation includes HFCs used in metered-dose inhalers in its quota (phase down) mechanism to encourage their replacement with low GWP fluorinated gases or alternatives to fluorinated gases (i.e., dry powder inhalers). The Dossier Submitters note that by 1 July 2028, the Commission shall publish a report assessing the impact of the F-gas regulation (2024/573, article 35.4) on the health sector, including on the availability of metered dose inhalers for the delivery of pharmaceutical ingredients. The Dossier Submitters recommend that the Commission includes the implications of the proposed restriction of PFASs used in metered dose inhalers in that assessment since the low-GWP propellant HFO-1234ze (which is proposed to be restricted with a transitional period of 5 years + 18 months) was previously identified as a key long term alternative to HFCs in metered dose inhalers in the Commissions impact assessment for the review of the F-gas regulation (EC 2022b). The Dossier Submitters also note that the recitals of the F-gas regulation (Recital 20) identify that cooperation between the Commission, competent authorities in Member States and the European Medicines Agency will be needed to facilitate the substitution of HFCs in metered dose inhalers to cleaner alternatives.

5kk) Semifluorinated alkanes as excipients in medicinal products. This use of semifluorinated alkanes is applicable specifically for ophthalmic and dermatological therapies.

5pp) Media for liquid-liquid separation processes comprise coalescence applications that are used for liquid-liquid separation of various solvents or corrosive chemicals at industrial sites.

Paragraph 6:

6c) The derogation covers use in implantable medical devices. A non-exhaustive list of implantable medical devices where PFASs are commonly used can be found in Table A.116. in Appendix A.3.10.

6f) The derogation is intended to allow the continued use of fluoropolymers and perfluoropolyethers in transport vehicles in applications where they are necessary for safety or environmental performance of vehicles. Rather than list specific identified uses in the derogation a more practical (i.e., manageable and enforceable) approach was to limit the permissible derogated uses (e.g. in vehicle systems, components or separate technical units) to only those that were within the scope of existing EU 'type approval' legislation for transport vehicles, where these requirements exist.

On this basis, continued uses of fluoropolymers and perfluoropolyethers would, by definition, only be possible in aspects of a vehicle (i.e. vehicle sub-systems) that are within the scope of type approval legislation. Type approval legislation is inherently focussed on achieving minimum standards of safety or environmental performance, such as in braking systems, passenger restraint, lighting/signalling and emission control systems.

Use of fluoropolymers or perfluoropolyethers in an aspect of a transport vehicle outside of type approval legislation, i.e., for cosmetic purposes such as stain resistance, would not be permitted under the proposed conditions of the 'type approval' derogation for transport vehicles.

Whilst EU type approval legislation is available for many of the transport vehicles included in the scope of transport, certain types of transport vehicle may not be subject to type approval legislation in the EU. It should still be possible for these vehicles to benefit from a derogation related use of fluoropolymers or perfluoropolyethers related to safety or environmental performance.

The Dossier Submitters note that the accompanying ancillary requirements for downstream users benefitting from such a derogation list in paragraph 8 would help to ensure that fluoropolymers and perfluoropolyethers were only used when alternatives were not suitable (i.e., the requirement for a downstream user to provide a 'justification for the use').

Paragraph 'i' of the proposed derogation is intended to apply to vehicle types that are subject to EU type approval legislation. *This legislation exists for the majority of vehicle types in the EU.* Paragraph 'ii' of the proposed derogation is intended to apply only to transport vehicles that are not subject to EU type approval.

(*) Where appropriate, the scope of the derogation could be adjusted (i.e., broadened or narrowed) depending on the conclusions of the assessments in other 'transport-related' sectors, such as sealing applications, energy, lubricants, electronics and semiconductors and technical textiles. HVACR systems in vehicles are subject to their own specific approach to use-specific derogations and are not foreseen to be included with the scope of this derogation.

6g) This derogation covers the professional and industrial use of vapor phase soldering for electronics, in which vapour is used to transfer heat to solder paste e.g. for soldering of capacitors, resistors, integrated circuit chips and more on a printed circuit board.

6h) This derogation covers the use of fluoropolymers and PFPE in wires, cables and connectors.

6i) This derogation covers the use of insulation material of electronic components. The understanding of insulation is related to the low dielectric constant and high thermal resistance. The derogation excludes the use of PFAS in wires, cables and connectors which are covered under a separate derogation. Covered is the use in other insulation material used in transducers or surge protection devices.

6j) The derogation covers the use of anti-drip agents in plastics of electronic components. PTFE can be added to PC/ABS plastics as an anti-drip agent and flame retardant e.g. in speakers, phones or other electronics.

6k) The derogation covers the use of fluoropolymers and PFPE in MEA or similar membrane assemblies e.g. ODC incl. membrane in Fuel cells and electrolysers in the MEA (PEM). This derogation does not cover piping, gaskets, bipolar plates or other seals outside of the assemblies. Examples of fuel cells and electrolysers covered are PEM, AWE, AEM, Direct-methanol & Chlor-alkali.

6l) The derogation covers the use of fluoropolymers in separator coatings for batteries.

6m) The derogation for PTFE nozzles in switchgears and circuit breakers encompass nozzles which are used in order to disrupt the arc (disrupt current) in high voltage applications (above 145 kV) by release of fluorine.

6n) The derogation covers fluoropolymers used for front- and backsheets in photovoltaic cells and include all uses of photovoltaic cells that convert sunlight into electricity by transport of electrons. This derogation does not cover solar collectors or similar applications that collect heat. Electronics in the photovoltaic cell is not covered by this derogation as this will be covered in Electronics and Semiconductor sector.

6o) The derogation on polymeric PFAS (fluoropolymers and perfluoropolyethers) in bridge and building bearings relates to bearings that are in place, often to secure bridges or buildings from collapsing due to natural disasters such as earthquakes or landslides.

6p) The term "sealing applications", for the purpose of this restriction, encompasses all applications of fluoropolymers (FPs) and perfluoropolyethers (PFPEs) where these are used to:

- to prevent or mitigate the unintended migration of substances from one area to another (e.g. leakage);
- contain pressure;
- exclude contamination.

The use should be understood as generic and is intended to apply across different use sectors. The use of FPs and PFPEs in sealing applications involves different actors along the supply/value chain and comprises uses of FPs and PFPEs as substances/mixtures, in the production of FP or PFPE containing articles and their consequent article service life, typically as component parts in (complex) objects. The proposed derogation for sealing applications in industrial uses is intended, as follows:

1. To allow the continued industrial use of substances/mixtures (FPs and PFPEs) for the production of sealing application articles (i.e., o-rings, gaskets) *i.e., the activities typically conducted by a plastics 'converter';*

2. To allow the placing on the market (including imports) of articles containing FPs/PFPEs for sealing applications for further industrial use (i.e., assembly into complex objects or further processing) but not for consumer/professional uses;

3. To allow articles containing FPs and PFPEs in sealing applications to be assembled into complex objects where the assembly of the complex object is at industrial sites/installations (but not use of the articles by professionals or consumers);

4. Allow the placing on the market (including imports) and use of complex objects (i.e., semi-finished or final products) containing FP/PFPEs in articles in sealing applications (e.g. pumps, transport vehicles) for (i) industrial uses and (ii) for 'end uses outside of an industrial site/industrial installation'.

The Dossier Submitters consider that the service life of an industrially produced complex object is consistent with the term 'industrial use' of a FP/PFPE article irrespective of whether the complex product is owned/operated by a professional user or a consumer. This is on the basis that whilst the FP/PFPE article is 'used' during the assembly of the product, the consumer or professional operating the product during its service life would not be required to 'interact' with the sealing application in the product for the product to fulfil its intended function. For example, sealing applications in consumer HVACR equipment, EV batteries or in the engines of motor vehicles, etc. The derogation period allows sufficient time for developing, certifying and distributing alternative materials for sealing applications.

6q) The term "machinery applications", for the purpose of this restriction, encompasses all applications of fluoropolymers (FPs) and perfluoropolyethers (PFPEs) not covered elsewhere and where these are used as

- Self-lubricating/low-friction components (either entirely made from FP/PFPEs or coated with them)
- Structural elements
- Coatings for protection/durability

The use should be understood as generic and is intended to apply across different use sectors. The use of FPs and PFPEs in machinery applications involves different actors along the supply/value chain and comprises uses of FPs and PFPEs as substances/mixtures, in the production of FP or PFPE containing articles and their consequent article service life, typically as component parts in (complex) objects. The proposed derogation for machinery applications in industrial uses is intended, as follows:

1. To allow the continued industrial use of substances/mixtures (FPs and PFPEs) for the production of articles (e.g. the production of plain bearings from FP or PFPE-feedstock) i.e., the activities typically conducted by a plastics 'converter';

2. To allow the placing on the market (including imports) of articles containing FPs/PFPEs for machinery applications for further industrial use (i.e., assembly into complex objects or further processing) but not for consumer/professional uses;
3. To allow articles containing FPs and PFPEs in machinery applications to be assembled into complex objects where the assembly of the complex object is at industrial sites/installations (but not use of the articles by professionals or consumers);
4. Allow the placing on the market (including imports) and use of complex objects (i.e., semi-finished or final products) containing FP/PFPEs in articles in machinery applications for (i) industrial uses and (ii) for 'end uses outside of an industrial site/industrial installation'.

The Dossier Submitters consider that the service life of an industrially produced complex object is consistent with the term 'industrial use' of a FP/PFPE article irrespective of whether the complex product is owned/operated by a professional user or a consumer. This is on the basis that whilst the FP/PFPE article is 'used' during the assembly of the product, the consumer or professional operating the product during its service life would not be required to 'interact' with the machinery application in the product for the product to fulfil its intended function. For example, machinery applications in household appliances. The derogation period allows sufficient time for developing, certifying and distributing alternative materials for machinery applications.

6r) Coating in release liners and backing film in transdermal patches. This derogation covers the PFAS coating in release liners and backing film in transdermal patches only.

6s) Blisters. This derogation covers fluoropolymers in blister for solid oral dosage formulations only.

6t) Coated rubber stoppers in vials/flasks. This derogation covers fluoropolymer coated rubbers stoppers in vials or flasks in for injectable medicinal products only.

6u) The derogation covers fluoropolymer coated canisters (drug delivery device) in pressurized metered-dose inhalers (pMDIs). The propellants (excipients) used in these canisters are covered by a separate derogation (under 5kk).

6v) Coated plungers. This derogation covers fluoropolymer coated plungers in pre-filled syringes only.

6w) Pre-filled injection. This derogation covers PFAS in injection pens & autoinjectors only.

6y) Filtration and separation media for 'water treatment and purification' include media used for drinking water treatment as well as the production of various grades of purified water, including ultrapure water, used for various industrial processes. It also includes filtration and separation media used for wastewater treatment.

Paragraph 7:

Reporting requirements are proposed for derogations with a duration of 13.5 years or time-unlimited as well as for all applications of fluorinated gases, with a view of creating an understanding of the magnitude of continuing emissions as well as the progress made in relation to substitution, see section 2.5 for further details. Reporting shall take place on an annual basis to the European Chemicals Agency (ECHA), referred to as "the Agency" in the context of the REACH Regulation.

These reporting obligations would help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes. In the event that the data reveals any concerns for the sector, further actions can be initiated either by reviewing this restriction or by acting under sector-specific legislation. The data will support the European Commission in case of a future review of this restriction. The reporting requirement will help to monitor whether there are any changes to uses and quantities which in turn may indicate changes in the emissions.

Reporting obligations shall apply to manufacturers, importers of PFASs and PFAS containing articles as well as formulators. The Dossier Submitters are aware that the formulator is, in contrast to the downstream user, not defined in the REACH Regulation. However, reporting by all downstream users is not considered practical by the Dossier Submitters. Manufacturers and importers often lack detailed knowledge on the whole supply chain, in particular if these are complex. Limiting the reporting obligation only to these actors might not provide sufficient use information to enable reviewing of the derogations. Formulators are usually the first downstream users of a substance and already have a good knowledge of the remaining supply chain and the (end)uses of substance. Therefore, it is proposed to include formulators, but not further downstream users in the reporting obligation.

Paragraph 8:

The Dossier Submitters propose that manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any derogation according to paragraph 5 or 6 prepare a site-specific management plan, outlining which PFASs are used in which quantities and in which products, see section 2.5 for further details. Such polymeric PFASs are often part of materials used in various equipment at a company site. At the end of their lifetime such equipment should be dismantled and the different materials managed safely (e.g. sent for appropriate disposal or recycled) as it is known that improper treatment of polymeric and other PFASs when waste may result in the formation and release to the environment of non-polymeric PFASs. This requirement will support enforcement authorities during inspections as it will help identifying the relevant PFAS-containing products. The requirement to justify the use of PFASs (i.e. that there remain no suitable alternatives in a specific use during an applicable derogation period) and to provide information on the operational conditions and the safe disposal shall raise the awareness of the actors that PFASs should only be used where they cannot be avoided and shall support the safe use and in particular the safe disposal, ensuring that emissions into the environment are minimised. The Dossier Submitters understand these plans to be a tool to ensure users of fluoropolymers and perfluoropolyethers to adequately assess all life cycle stages of their PFAS-containing products during the transitional period and support the implementation of suitable risk management measures and operational conditions.

Paragraph 9:

This restriction proposal in particular does not cover the use of PFASs in fire-fighting foams, which is assessed in a separate restriction proposal. It is not meant to overrule the firefighting foam restriction proposal.

Existing restrictions in Annex XVII with a more specific substance scope (e.g. C9-C14 PFCAs in entry no. 68) take precedence over more generic restrictions (e.g. UPFAS, PFAS in FFF). However, uses not covered by previous restrictions in Annex XVII relating to specific PFAS (e.g. PFHxA) fall under this restriction. An exception to this are entries 28-30 of Annex XVII, as these are less strict. Thus, in this case the proposed restriction should take precedence over them.

Other Union legislation addressing substances within the scope of this restriction shall be adhered to notwithstanding this restriction, i.e. they are considered complementary. Section 2.2 gives a non-exhaustive overview over these legislations.

## Considerations on the review clause

The duration of use-specific derogations under RO2 were proposed based on whether it was concluded in the analysis of alternatives that there was (i) high substitution potential at entry into force (EiF) - transitional period of 18 months proposed, (ii) low substitution potential at entry into force but high substitution potential within five years after EiF – derogation of five years (after the end of the 18 months transitional period) proposed and (iii) low substitution potential within five years after EiF – derogation of 12 years (af-ter the end of the 18 months transitional period) proposed.

When assessing the corresponding environmental and economic impacts of transitional periods, the Dossier Submitters assume that suitable alternatives will become available within the proposed transitional period. This assumption is based on the information available to the Dossier Submitters including the information received in the consultation on the Annex XV report. Nevertheless, as outlined in Annex F (Assumptions, uncertainties and sensitivities) uncertainties with regard to the development of suitable alternatives within derogation periods remain, in many cases, high – particularly where a 12-year derogation period has been proposed, e.g. due to the absence of, or conflicting, information on the suitability of alternatives for a specific-use.

The Dossier Submitters have identified several specific uses where there is a greater likelihood that suitable alternatives will not become available during a proposed 12-year transition period, in particular for certain uses of fluoropolymers, e.g. certain sealing applications, lubricants, batteries etc., including the use of PFAS-containing substances or mixtures for the ongoing maintenance or repair of legacy complex objects that have very long service lives (such as aircraft), where certification and re-qualification challenges may further complicate substitution (similar to, but outside of the scope, of the assessment of PFAS-containing spare parts, for spare parts see Annex E.3.3). The Dossier Submitters also note that cumulative effects of substituting PFAS in multiple applications in parallel adds an additional layer of complexity to the substitution process (see end of section 2.4.1.1). However, in order to avoid any incentive for delaying the development of suitable alternatives, the Dossier Submitters prefer to retain the proposed 12-year derogations for these applications, in line with the developed approach rather than propose longer or indefinite derogations for these uses.

Nevertheless, the Dossier Submitters recognise that in the event that transition periods for a specific-use expire but - despite all efforts - suitable alternatives are not available, this would result in significant socio-economic costs, particularly in sectors that are important for EU strategic autonomy and competitiveness. With this scenario in mind, many stakeholders, in their comments to the consultation on the Annex XV report (e.g. comment IDs #4265, 4442, 4453, 4584, 6005, 6100, 6213, 6624, 7285, 7379, 7426, 7544, 7846, 8040, 8047, 8394, 8518, 8632, 8661, 8666, 8728, 8808, 8871, 8945, 9030, 9043, 9048, 9210, 9224, 9233, 9245, 9262, 9378, 9387, 9388, 9396, 9403, 9443, 9546), suggest the introduction of review clauses alongside the proposed derogations, in particular for applications, for which suitable alternatives do not yet exist, e.g. PPE, batteries, coil-coatings, semiconductor manufacturing, certain technical textiles, certain applications of fluorinated gases, military applications, etc. This would, they argue, support ongoing business decisions and investments in the EU.

The Dossier Submitters agree that, given the uncertainties associated with the suitability of alternatives in certain uses, including for the maintenance and repair of legacy complex objects with very long service lives, a review of derogations prior to their expiration could be appropriate to avoid unintended socio-economic impacts but note that the Commission can review existing restrictions in Annex XVII at any time and acknowledge that it would be up to the Commission to consider the introduction of such a review period in this specific restriction. Therefore, the Dossier Submitters do not consider it to be in their remit to include a review clause in the proposed restriction, yet it is deemed an appropriate tool in the above-mentioned cases.

As indicated at the end of section 2.4.1.1, the Dossier Submitters recommend that the identified cumulative impacts of the restriction proposal are taken into consideration in an eventual review.

The information provided by manufacturers, importers and downstream users via the proposed reporting requirements for ongoing placing on the market of PFASs under an indefinite or 13.5 year derogations (as proposed in paragraph 7 of the draft entry text) will provide relevant information for monitoring the need for a review of a derogation after entry into force (see also section 2.5).

Crucially, if relevant, information on the progress towards the substitution of PFASs will be required to support any review of a derogation for a specific use. The requested information on the quantity of PFASs placed on the market in each calendar year will provide an indirect measure of the success of substitution (reduction in quantities placed on the market over time) as well as highlighting where substitution appears most challenging (quantities placed on the market do not decline). In addition, the Dossier Submitters note that efforts made by companies on research and development of alternatives are also intended to be documented in a site-specific management plan (as proposed in paragraph 8 of the draft entry text). The site-specific management plan is also intended to contain a justification for the continued use of PFASs in the respective use (i.e. an analysis of alternatives). The information contained in these management plans could serve as a basis for any review of the need to extend a derogation for certain uses of PFASs together with other information, e.g. from the public domain. Should any review clause be envisaged, the Dossier Submitters recommend that this is accompanied by an appropriate mechanism to monitor the ongoing substitution efforts of affected stakeholders in order to allow an evidence-based decision on the need to prolong a derogation for a specific-use.

Finally, the Dossier Submitters caution that the existence of a review clause could potentially undermine the objectives of the proposed restriction as, unless rigorously assessed, its existence could remove the incentive for all users to substitute PFASs; an incentive that is currently provided by the proposed unambiguous phase-out date.

### Approach to the upstream supply chain for derogated uses

To allow a derogated use to be possible, the upstream supply chain should be able to produce the PFAS substance(s) necessary for these derogated uses. In most of the uses that are derogated, a specific PFAS is used due to a specific function in the product. This specific PFAS substance needs to be produced in the upstream supply chain. Such production often starts from starting materials that are also PFAS, which go through different chemical modification steps, where the starting materials are converted into different PFAS intermediates, until the required specific PFAS for the target use is produced. The derogation is intended to include PFAS building blocks and intermediates in all steps in the process from the starting materials to the final PFAS substances used and the products in which these substances ultimately are used for the derogated use (either as a substance, mixture, article on its own or in a complex object).

The Dossier Submitters' intention with a derogation for a specific use is to also implicitly derogate the upstream supply chain in using the PFAS that ultimately is being applied in the derogated use (the base materials, also if this starting substance may not be the exact same substance as the one ending up in the final product). This is important, as downstream users may not always be aware of all the processes and uses of (raw materials in) PFASs in the upstream supply chain that are present in their products (comment IDs #9376, 9485). This derogation of the upstream supply chain only applies to the PFAS substances used in a derogated use, as well as the building block needed produce this PFAS substance (i.e. starting materials and intermediates). It does not encompass the use of PFAS in e.g. equipment and instruments used to produce for the derogated use, or solvents and auxiliary chemicals (those that are not intentionally present in the end product). Such uses of PFAS in the upstream supply chain are covered in specific sectors of the dossier, e.g. broader industrial uses, sealing applications and machinery applications.

Several stakeholders also mention the effects on the supply chain of the ban and the possible impact on uses for which a derogation is proposed (e.g. comment ID #4245, 4302, 4543, 6208, 6514, 7920, 8046, 8539, 9149, 9376, 9489 and a number of confidential comments). Depending on the use, supply chains may be long and complex, e.g. in sectors in which complex objects are assembled and used, like in the pump sector and the medtech sector (comment IDs #4245, 4302, 7920). The socio-economic impacts of these complex supply chains are also addressed in more detail in the section on cumulative impacts (see 2.4.1.1). Also, the (lack of) communication in the supply chain (e.g. upstream suppliers not informing downstream users on the presence of PFAS in (parts of) their products) is indicated as a difficulty (comment ID #4543). However, the proposal to derogate the upstream supply chain does not dismiss suppliers from their responsibility to indicate that PFAS is present in their products that are intended to be used for derogated uses. Good chemicals management at company level implies that information on the chemicals which have been used in the manufacture and may be found in a product should already be known. It is assumed that there is efficient information flow on the chemicals in the supply chain, and if so, companies should be able to determine whether PFASs are found in their products or not.

### Product and process orientated research and development (PPORD)

In REACH art. 3(22) product and process orientated research and development is defined as any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance. Art. 67 (1) indicates that Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

Several stakeholders (e.g. comment ID #4041, 4455, 4503, 6436, 6708, 7142, 7281, 7756, 7875, 8804, 9063, 9365, 9453, and some confidential comments) mention that a derogation for PPORD is necessary. Most of those stakeholders are active in the field of pharmaceuticals, but also in the field of energy and electronics comments have mentioned that PPORD needed to be addressed to avoid unwanted consequences for the possibility to develop products for derogated uses. The reason indicated by stakeholders for the need for a derogation is that to allow all stages in the development of a product in the EU/EEA before market introduction for derogated uses, PPORD activities should be derogated. Excluding the step of PPORD from this development chain, would hamper the final step in research and development for a derogated application of PFAS, as (manufacturing for (clinical)) testing and would not be possible with a restriction in place that does not specifically address PPORD.

For comparison, the Dossier Submitters note that the absence of an exemption for clinical trials in paragraph 4(b) of the REACH restriction for synthetic polymer microparticles (Annex XVII entry 78, also known as the Microplastic restriction) is currently being addressed by the European Commission. The Commission services are currently preparing a Correcting Act to change the wording of this paragraph so that the placing on the market of medicinal products used in clinical trials is included in the derogation (EC, 2025).

To avoid a similar problem with a restriction on PFAS, the Dossier Submitters propose a time-unlimited derogation for PPORD activities. Effectively, this time-unlimited derogation for PPORD for derogated uses will cease once the derogation period for a specific use ends.

A PPORD exemption for registration under REACH art. 9 is for five years. The strict conditions for a PPORD registration exemption as laid down in REACH art. 9, will also apply to this derogation, with special emphasis on art. 9(4) in which conditions can be imposed by ECHA on the safe use and disposal (e.g. avoiding emissions) on the level of an individual PPORD. As the amount that may need to be produced for PPORD purposes may vary per derogated use, the Dossier Submitter does not propose an upper limit to the amount of (product containing) PFAS that can be produced under PPORD. This should be done on a case-by-case basis.

### Scientific research and development (SR&D)

REACH art. 67(1) exempts Scientific research and development (SR&D) from restrictions. SR&D is defined in REACH art. 3(23) as any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year. According to the ECHA Guidance[5], SR&D may include any experimental research or analytical activities at a laboratory scale such as synthesis and testing of application of chemicals, release tests, etc., as well as the use of the substances in monitoring and routine quality control, calibration of laboratory equipment or in vitro diagnostics at a laboratory scale under controlled conditions.

The SR&D exemption is understood to cover both substances and substances in articles (e.g. fluoropolymers). Fluoropolymers are frequently used as materials in equipment and instruments in research-related activities.

Several stakeholder comments (e.g. comment IDs #4417, 4438, 4447, 4505, 6362, 7099, 7337, 7413, 7491, 7763, 7886, 8184, 8540, 8623, 8698, 9063 and other confidential comments) have highlighted uses of PFAS substances within SR&D. The uses include reagents, solvents, filter membranes, reference standards, extraction agents, additives, digestion tubes, sealing, O-rings, lubricants, reagent and solvent transport tubing and fittings, coatings, pipettes, intermediates, processing aids and sensors among others, all of which are used to facilitate sample preparation, synthesis, diagnostics, chemical analysis and research in general at a scientific level.

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[5] https://op.europa.eu/en/publication-detail/-/publication/80d0ceb9-deee-11e7-9749-01aa75ed71a1/language-en, date of access: 2025-05-22.

# 1. Problem identification

Per- and polyfluoroalkyl substances (PFASs) are a group of thousands of synthetic chemicals that are used widely in the EU as well as in the rest of the world, in a broad range of applications such as textiles, food packaging, lubricants, refrigerants, and electronics. All PFASs in the scope of this restriction proposal are either very persistent themselves, or degrade into very persistent PFASs in the environment. This is the key hazardous property common to all PFASs in this restriction proposal. Consequently, if releases of PFASs are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects become inevitable. In such an event these exposures are practically irreversible as it is technically extremely difficult, if at all possible, to remove PFASs from the environment.

Most PFASs, including persistent PFAS metabolites, are either mobile in water or accumulate in biota, and both lead to unavoidable exposure of humans and the environment. For example, it has been documented that contamination of groundwater, surface water (freshwater, estuarine and marine) and biota with PFASs is already widespread. Drinking water contamination is already widely reported and it is very difficult and costly to remove PFASs. Deterioration of drinking water sources represents a societal concern, especially as drinking water is gradually becoming less available due to the effects of global warming. Plants also accumulate PFASs via soil and water. Consumption of plant material, e.g. grains and vegetables either as roots or above ground plant parts, function as a source of PFASs to humans and animals. In both humans and animals, PFASs are transferred to the foetus via the placenta and to the offspring via breast milk. Hence, also offspring exposure is unavoidable.

Some PFASs are distributed to remote areas and pristine environments by long range transport processes. Some PFASs are gases. Once released, these PFASs are distributed around the globe where they contribute substantially to global warming and climate change.

The most thoroughly researched PFASs (PFOS and PFOA) are suspected carcinogens, cause harm to the developing child (as a result of intergenerational exposure) and trigger effects at low concentrations in organs such as the liver or in the immune system. There are also data identifying some PFASs as potential endocrine disruptors, and the environmental effects of some PFASs (e.g. 6:2 FTOH) are sufficient to warrant classification of these PFASs as hazardous to the aquatic environment. Although for most PFASs there are insufficient data to adequately assess their effects on human health and the environment, increasing research efforts that progressed beyond PFOS and PFOA reported similar adverse effects for other PFASs. Hence, there is a growing concern for the harmful effects of the complete PFAS family, given that concerns similar to the well-studied PFASs may be also expected for the currently less studied substances. Adverse effects resulting from 'combined exposure' to complex mixtures of PFASs are likely for both humans and wildlife. However, these effects cannot currently be assessed quantitatively with sufficient certainty for regulatory purposes. A group approach to regulation of PFASs is efficient to address this complex interplay of concerns.

This chapter defines PFASs and characterises environmental and human health hazards and risks of the use of PFASs in a broad range of applications.

## 1.1. Hazard, exposure/emissions and risk

### 1.1.1. Identity of the substance(s), and physical and chemical properties

For the purpose of this restriction proposal PFASs are defined as substances that contain at least one fully fluorinated methyl ($CF_3$-) or methylene (-$CF_2$-) carbon atom, without any H/Cl/Br/I attached to it. This definition is similar to the OECD definition, derived in 2021, which reads as: "PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–$CF_3$) or a perfluorinated methylene group (–$CF_2$–) is a PFAS." (OECD, 2021). For the restriction proposal however one exception is introduced (see rationale given below). The exception concerns certain fully degradable PFASs subgroups that only contain some specific structural elements.

For the purpose of the Annex XVII restriction entry, the Dossier Submitters propose the following definition of PFASs:

> Any substance that contains at least one fully fluorinated methyl ($CF_3$-) or methylene (-$CF_2$-) carbon atom (without any H/Cl/Br/I attached to it).
>
> A substance that only contains the following structural elements is excluded from the scope of the proposed restriction:
>
> $CF_3$-X or X-$CF_2$-X',
>
> where X = -OR or -NRR' and
>
> X' = methyl (-$CH_3$), methylene (-$CH_2$-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R''';
>
> and where R/R'/R''/R''' is a hydrogen (-H), methyl (-$CH_3$), methylene (-$CH_2$-), an aromatic group or a carbonyl group (-C(O)-).

PFASs, according to the definition used in this restriction proposal, form a broad group of substances, including volatile as well as non-volatile PFASs, anionic, cationic, zwitterionic and non-ionic substances, polymers of different kinds as well as non-polymers, amphoteric liquids (surfactants), etc., with various chain-lengths and degree of fluorination. The group of PFASs therefore cannot be characterized by (a) specific (range of) physicochemical properties. Nevertheless, they (or their PFAS degradation products) share very high persistence as a common characteristic. Information about the physicochemical properties of a selection of PFASs is provided in Annex B.1.2.

This restriction proposal covers all substances defined above as substances on their own, as a constituent (including as impurity or additive) as well as in mixtures and in articles.

Rationale

Figure 1 shows the main PFAS subgroups as defined in the OECD 2021 report, including the division in subgroups of stable metabolites or 'arrowheads' (perfluoroalkyl acids or PFAAs), and the precursors to these PFAAs. The terminal degradation products are often referred to as **arrowhead substances**, while the parent substances degrading to the arrowheads are referred to as **precursors**. The term **related substance(s)** is used interchangeably with the term precursors. It should be noted that the polyfluoroalkyl acids (PolyFAAs) and most of the other PFASs are not necessarily all direct precursors to PFAAs in the short term, but will ultimately somewhere in their life cycle be able to form PFAAs over time. The figure is adapted from Figure 9 in the OECD 2021 report, where more details on the grouping and nomenclature of PFASs are available.

Figure 1. Main PFAS subgroups.Including the subgroup of stable metabolites (PFAAs) or 'arrowheads' (      ) and the precursors to the PFAAs (        ). It

should be noted that the Polyfluoroalkyl acids (PolyFAAs) and most of the other PFASs are not necessarily all direct precursors to PFAAs in the short term but will ultimately somewhere in their life cycle be able to contribute to the release of PFAAs. Figure adapted from OECD (2021) – see Figure 9 therein for more details on the grouping and nomenclature.

# BACKGROUND DOCUMENT – Per- and polyfluoroalkyl substances (PFASs)

Per- and polyfluoroalkyl substances (PFASs) are a group of synthetic organic chemicals that have been in use since the 1950s, i.e. as ingredients or intermediates for industrial and consumer applications. They have attracted much public attention since the late 1990s and early 2000s, when the hazards and ubiquitous occurrence in the environment of two PFASs, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), started to be reported and recognized. Early communications used many different terminologies for what nowadays are called PFASs (e.g. per- and polyfluorinated chemicals, perfluorinated organics, perfluorochemical surfactants or highly fluorinated compounds).

Research and risk management measures have expanded from PFOA and PFOS to a wider range of PFASs, and regulators and scientists across the globe show a growing concern for legacy as well as novel PFASs. A study by the OECD/UNEP Global PFC Group identified 4 730 CAS-numbers associated with individual PFASs or PFAS mixtures (OECD, 2018). A recent analysis of PFASs registered under REACH and/or notified to the CLP classification and labelling inventory in 2019 and comparison with the OECD/UNEP list revealed that there may be as many as >9 000 different individual PFASs. The US EPA has a master list of PFASs which combines information from several existing lists into one consolidated list. In 2019 this list contained 6 330 different PFASs, while in July 2022 it contained 12 034 PFAS. Hence, a fair statement is that the current number of PFASs is at least 10 000. Recent information suggests that the number of substances fulfilling the OECD definition may theoretically be up to 6 million ((Schymanski et al., 2023)).

In perfluoroalkyl substances all C-H bonds have been replaced by C-F, while in polyfluoroalkyl substances two or more C-H bonds have been replaced by C-F but some C-H bonds still remain in the molecular structure. Polyfluoroalkyl substances containing at least one perfluorinated moiety (-CF$_2$- or -CF$_3$, not being directly attached to -H, -Cl, -Br or -I) are within the definition.

For clarification, a perfluorinated olefinic carbon atom (=CF$_2$) or an aromatic ring bound directly to an F-atom (–CF=) does not fulfil the PFAS definition alone (text from OECD (2021). Consequently, olefins and aromatic substances would need additional fluoroalkyl elements to be regarded as PFASs.

PFASs can be divided into (functional) subgroups in several ways. Figure 1 provides one way to differentiate, where the subgrouping is based on main chemical moieties present. Further ways to differentiate are for example carbon chain length and non-polymeric vs polymeric structures. The non-polymeric PFASs comprise a range of diverse molecules and include, amongst others, perfluoroalkyl carboxylic acids (PFCAs e.g. PFOA), perfluoroalkane sulfonic acids (PFSAs e.g. PFOS)[6], fluorotelomer-based compounds (e.g. 6:2 FTOH), per- and polyfluoroalkanes (e.g. perfluorooctane), perfluorotrialkylamines and per- and polyfluoroalkyl ether compounds, such as perfluoroalkyl ether carboxylic acids (PFECAs, e.g. HFPO-DA). Within the polymeric PFAS group, fluoropolymers (polymers consisting of a polymeric fluorinated carbon backbone), side-chain fluorinated polymers (polymers consisting of non-fluorinated polymer backbones with per- or polyfluoroalkyl/alkyl ether side-chains attached; (OECD, 2022b)) and perfluoropolyethers (PFPEs; ether polymer backbone with F atoms directly attached) are included.

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[6] A frequently used division is based on alkyl chain length where perfluoroalkyl carboxylic acids (PFCAs) with seven or more perfluorinated carbons and PFSAs with six or more perfluorinated carbons are considered as "long-chain" PFCAs and PFSAs, respectively, and those with shorter perfluoroalkyl chains "short-chain" PFCAs and PFSAs (OECD, 2021). It is noted that this definition has not been extended to other PFAAs nor to other PFASs. In this document, alkyl chain length of PFCAs and PFSAs is indicated as C[number of carbons].

Fluoropolymers (FPs) and Perfluoropolyethers (PFPEs) are both polymers. However, they exhibit various different properties, see OECD (2022a). Both groups have different synthesis pathways/manufacturing processes - like side-chain fluorinated polymers also have a different synthesis pathway/manufacturing process. These subgroups share the overall concern of very high persistence and have different additional concerns, similar like for other subgroups, see our assessment of persistence of these structures under "Perfluoroalkylethers (PFAEs)" in section B.4.1.2. in Annex B. The Dossier Submitters' evaluations are supported by e.g. Wang et al. (2017) who explained that perfluoroalkyl ($C_nF_{2n+1}$-) and perfluoroether ($C_nF_{2n+1}{-}O{-}C_mF_{2m+1}$-) moieties are very persistent under natural conditions.

Comparing PFPEs and FPs in end of life stage, similarities are expected (as for all PFAS, polymeric or not), however, the exact fate will depend on the specific chemical composition. At least for some PFPEs it is expected that persistent arrowhead degradation products may form during incomplete incineration. PFPEs are usually liquid substances, and the Dossier Submitters have not received or found any information indicating that solid particle formation or degradation products may form from PFPEs. Hence, to the Dossier Submitters' current knowledge microplastic pollution is not an issue with PFPEs, since they are oils.

Far less information about the PFPEs was received in the consultation - both regarding manufacture, use, hazards and environmental fate. Consequently, far less text on PFPEs is in the dossier as well. Additional information about PFPEs may be found in the report "Per- and polyfluoroalkylether substances: identity, production and use" (NCM, 2020). Some additional information on PFPEs and their use in coatings, paints and varnishes can be found in an OECD report, issued in December 2023 (OECD, 2023). More additional information on PFPEs will become available in the OECD report ”Synthesis Report on Understanding Perfluoropolyethers (PFPEs) and Their Life Cycle”, expected to be issued in April 2024.

Some substances contain only a single $-CF_3$ group attached to carbon, and because of their structure they are potential precursors to trifluoroacetic acid (TFA). To this subgroup belong, amongst others, some fluorinated gases and active ingredients in biocides, plant protection products and pharmaceuticals containing a $-CF_3$ group bound to an aromatic ring. Fluorinated gases fulfilling the scope definition form the largest contribution by production volume to this subgroup.

The OECD definition of PFASs is based on chemical structure. Hazardous properties or risks are not part of it. The substance scope of the proposed restriction is additionally a concern-based one as it intends to cover PFASs that have a very high persistence, exceeding the criterion for very persistent (vP) according to Annex XIII of the REACH Regulation with the aim to address the concerns associated with the very high persistence of these substances.

Generally, PFASs are either very persistent themselves or will ultimately degrade to very persistent degradation products (so-called PFASs arrowheads). There are, however, substances belonging to a few specific PFAS subgroups with combinations of key structural elements that are expected not to form ultimately persistent PFAS arrowheads, to ultimately mineralize in the environment and therefore to be less persistent than other PFASs. Substances belonging to these PFAS subgroups have been shown to fully [7]☐ (see relevant available degradation data summarized in Annex B.4.1.4.) and thus do not form ultimately persistent PFAS arrowheads (perfluoroalkyl acids (PFAAs)). These PFAS subgroups are hence excluded from the scope definition of this restriction proposal. A schematic illustration of the excluded substance groups is depicted Figure 2, and some examples are presented in Figure 3.

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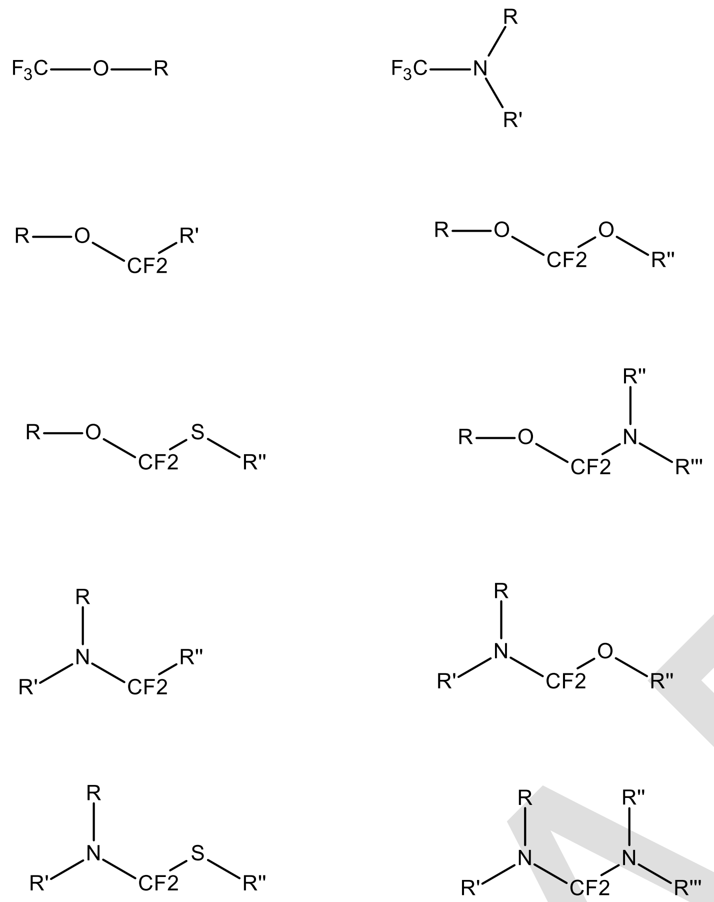
[7] Fully degrade implies mineralize to $CO_2$, $H_2O$ and HF, leaving no persistent fluorinated organic metabolites that would fulfil the scope definition.



R, R', R'', R''' = hydrogen (-H), methylene ($-CH_2-$), methyl ($-CH_3$), an aromatic group or a carbonyl group (-C(O)-)

**Figure 2. Substances excluded from the scope of the restriction proposal (schematic overview).**

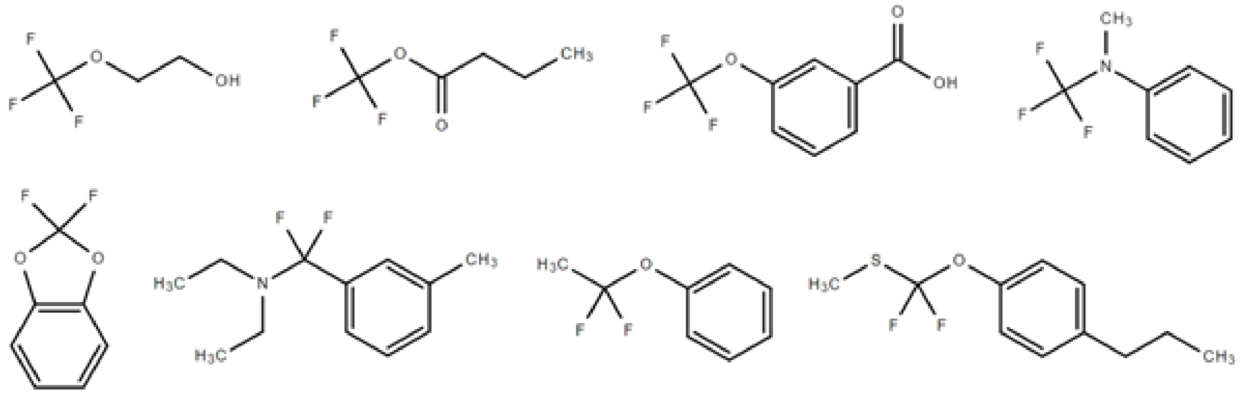


**Figure 3. Examples of PFASs that are excluded from the scope of the restriction proposal.**

### 1.1.2. **Justification for grouping**

PFASs are considered as a group because all members of the group share a common hazard and risk (described in sections 1.1.4 and 1.1.6). This is, in essence, the result of the very persistent property of the perfluorinated part(s) of PFAS molecules.

Specific PFASs have previously been assessed (and in some cases have been subject to risk management) on the basis of the PFAS moieties that they contain (see Annex B.1.3.). For example, PFOA is a very persistent (vP) substance that is the common final (terminal) product of the environmental (bio)degradation of various different PFASs which all contain the perfluoroheptyl moiety. PFASs have been allocated to subgroups based on their respective terminal degradation product (respective common perfluorinated moiety) (see Figure 1). Over sufficient time horizons all precursor substances will contribute to environmental stocks of their corresponding arrowhead substances (see Annex B.4.1.3. for further details). This grouping approach is acknowledged as a basis for risk assessment also by several scientists, who consider that regulation of PFASs on the basis of persistence alone should already suffice (see e.g. Cousins et al. (2020b); Scheringer et al. (2022)).

Based on the experience with European regulatory activities on PFASs since 2014, it is expected that PFASs restricted individually or per arrowhead group (e.g. PFOA and related substances) might simply be replaced with slightly different non-restricted PFASs (e.g. ADONA or HFPO-DA) with similar risks. This observation provides the main motivation to include all PFASs having equivalent hazard and risk in a single restriction proposal, to avoid regrettable substitution by other PFASs.

Some PFASs included in the scope of the proposed restriction may have a negligible or indeed no current use. However, such PFASs would need to be included in the scope, either because their use may increase as a result of becoming an alternative for other, restricted PFASs, or due to new uses.

To summarise, the grouping is based on structural similarity (common perfluoroalkyl moieties) that triggers equivalent hazards and risks among the substances covered, primarily related to the very persistent property of the substances (due to the parent compounds and/or degradation/transformation products). However, the grouping is also justified by the desire to avoid regrettable substitution and prevention of future exposures of those PFASs which are not currently in use.

### 1.1.3. **Classification and labelling**

Around 6 600 PFASs have a classification (mostly self-classification) for at least one environmental, human health, and/or physicochemical endpoint in ECHA's classification and labelling notifications database.

When looking specifically at human health endpoints considered of most concern following long-term exposure of humans (i.e. carcinogenicity (Carc.), mutagenicity (Muta.), reproductive toxicity (Repr.) including effects on or via lactation (Lact.), and specific target organ toxicity (STOT RE)), 357 PFASs have a classification for at least one of these five endpoints, of which 41 are harmonised classifications (Q4 2020), see Annex B.3. for more information.

With regard to the environmental hazards (hazardous to the aquatic environment and hazardous to ozone layer) 1 129 PFASs have a self-classification.

### 1.1.4. **Hazard assessment**

#### 1.1.4.1. Overview

PFASs is a broad term used to cover at least 10 000 specific chemical substances which have a wide range of uses. These uses are principally based around the carbon-fluorine bond which is particularly strong and highly persistent (see below section 1.1.4.2 on persistence, and Appendix 3 of the study on the use of PFASs in fire-fighting foams (Wood, 2020)). All PFASs in the scope of this restriction proposal are either very persistent themselves, or degrade into very persistent PFASs in the environment. In the case of fluoropolymers, they themselves are persistent and like for polymers in general, fluoropolymer microparticles can be formed during their use phase or end of life phase. Additionally, it is important to look at the whole life cycle of fluoropolymers. During their production and use monomers, oligomers, smaller polymers and by-products are emitted into the environment. During waste incineration at the end of life, non-polymeric PFASs can be formed and emitted. (see also Annex B.7.6).

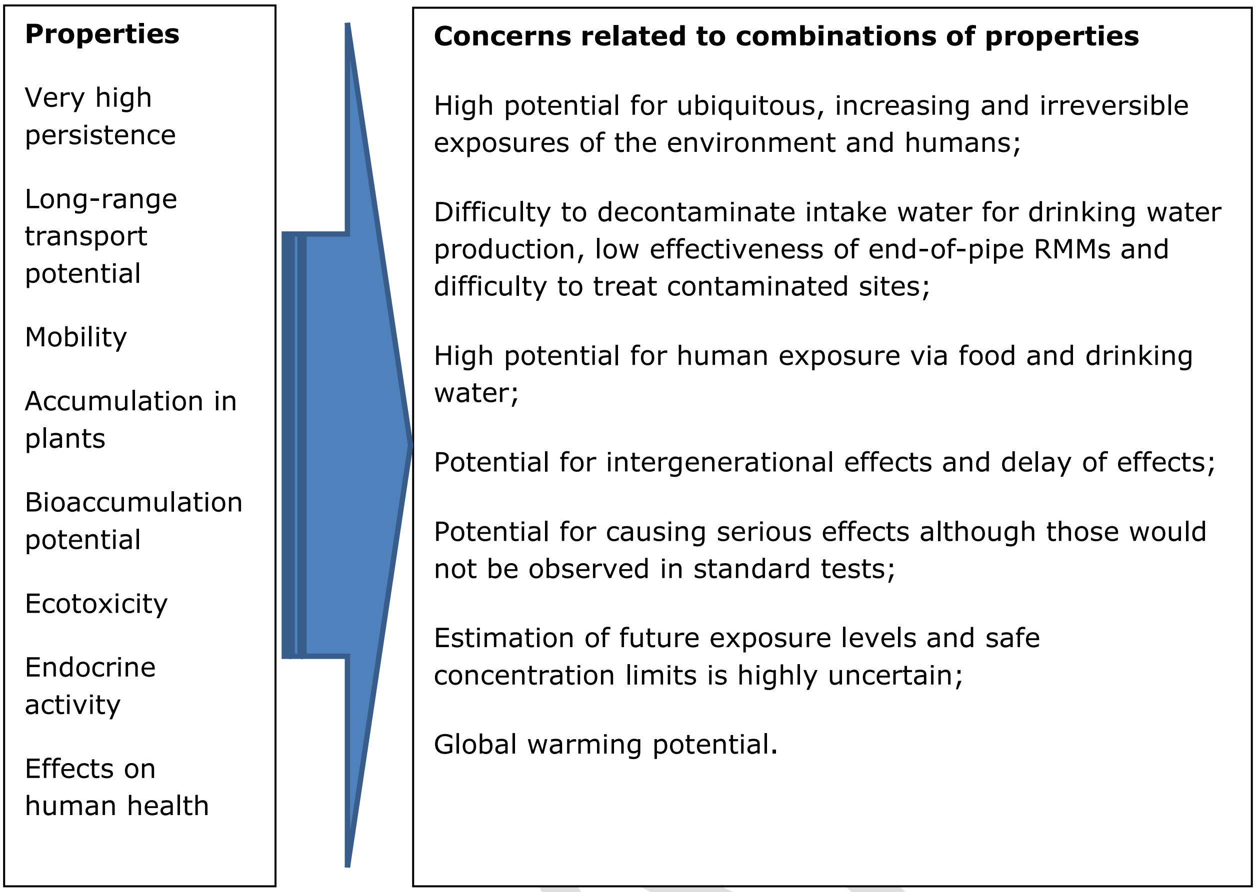
Persistence is the key hazardous property common to all PFASs in this restriction proposal. Further supporting concerns vary among these PFASs. These properties include bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects (sections 1.1.4.3-9) and concerns related to a combination of properties (section 1.1.4.10). Taken together this can create concerns where PFASs, emitted to the environment, reach and contaminate important resources such as groundwater, on which abundant literature is available (see also Annex B.4.2.).

Goldenman et al. (2019) indicate that the contamination may be poorly reversible or even irreversible, and may reach levels that could render natural resources such as soil and water unusable far into the future, resulting in continuous exposure and unavoidable harmful health effects, particularly for vulnerable populations, such as children.

There is evidence to suggest that exposure to PFASs can lead to adverse health effects in humans (by eating or drinking food or water contaminated by PFASs). In particular there are indications that the long-chain substances PFOS and PFOA can cause reproductive and developmental, liver and kidney, and immunological effects in laboratory animals. Furthermore, both chemicals have caused tumours in animal studies. The use of PFOS and PFOA is already regulated in the Stockholm Convention. Other PFASs like PFHxS, PFBS and HFPO-DA have been listed as SVHCs, based on there being an equivalent level of concern to the named groups of chemicals under the authorisation provisions under REACH (carcinogens, mutagens and reprotoxicants (CMRs) and persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) chemicals).

Based on the physical properties of PFASs (particularly mobility and persistence) along with identified health effects for some PFASs, PFASs represent a challenging environmental and human health hazard.

All PFASs that are in the scope of this restriction proposal are considered to be very persistent, either on the basis of their own very persistent properties or the very persistent properties of their terminal degradation product (arrowhead). Additional hazardous properties depend on the specific structure of a PFAS. Properties of concern identified in investigated PFASs as well as concerns resulting from specific combinations of properties are listed in Figure 4 and further described below.



**Properties**

Very high persistence

Long-range transport potential

Mobility

Accumulation in plants

Bioaccumulation potential

Ecotoxicity

Endocrine activity

Effects on human health

**Concerns related to combinations of properties**

High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;

Difficulty to decontaminate intake water for drinking water production, low effectiveness of end-of-pipe RMMs and difficulty to treat contaminated sites;

High potential for human exposure via food and drinking water;

Potential for intergenerational effects and delay of effects;

Potential for causing serious effects although those would not be observed in standard tests;

Estimation of future exposure levels and safe concentration limits is highly uncertain;

Global warming potential.

**Figure 4. PFAS properties and property-related concerns resulting from combinations of the properties.**

### 1.1.4.2. Persistence

As detailed in Annex B.4.1. on degradation, PFASs are among the most stable organic compounds. Common for all the PFASs is that they have perfluoroalkyl moieties present. These moieties resist environmental and metabolic degradation due to the very stable C-F bonds. As presented in Figure 1 and introduced in section 1.1.1, PFASs can be divided with regard to the hazard assessment into "precursors" and "arrowheads". The precursors are known or expected based on modelling to degrade on a timescale from hours to years to the arrowheads, such as e.g. PFCAs, PFECAs and PFSAs. There is a common understanding about grouping PFASs according to their stable degradation end-products (e.g. Cousins et al. (2020a)).

After gradual degradation of the non-fluorinated part, the degradation stops when only perfluorinated carbons, and often other moieties at their highest oxidation state and with high persistence, are left in the substance (see more in Annex B.4.1.).

Environmental degradation of the non-fluorinated moieties in PFAS precursors often leads to the formation of PFAS intermediates and ultimate degradation products with increased mobility in water and/or air via oxidative chemical and biochemical degradation processes in the environment, see description of the precursor degradation in Annex B.4.1.3.

Degradation half-lives of the arrowhead PFASs in the environment exceed the criteria for very persistent substances in Annex XIII to REACH by far. For example, PFAAs are key arrowheads in the environment, and if PFAAs degrade, they do it so slowly that it is not observable in standard tests.

The high persistence of PFASs is their main concern, for the following reasons:

The continuous use and release of these very persistent substances leads to sustained exposure and increasing stocks in the environment. The high persistence in the environment will lead, inevitably, after release to distribution of PFASs from one environmental compartment to another (e.g. from soil to freshwater to marine environment). Even if releases of PFASs are minimised now, PFASs will remain in the environment for a very long time (see further details in Annex B.4.). Furthermore, the combined historic releases of precursor PFASs form arrowhead PFASs over time. Therefore, the precursor stocks in the environment represent a long-term source of arrowhead substances, even if the releases of precursors are stopped. The longer the stock is allowed to increase, the less effective the emission reduction will become.

The increasing stock pollution will result in increasing likelihood that known and unknown effects occur, be it by a single chemical and/or in a mixture with other substances (e.g. Bil et al. (2021).

The persistence as the core concern of PFASs has also been pointed out by scientists for instance in the Helsingør Statement on PFASs (Scheringer et al., 2014) as well as the follow up Madrid statement (Blum et al., 2015). Cousins et al. (2019) suggested to regulate PFASs on the basis of their very high persistence only and has named this the "P-sufficient approach" to regulatory action. Persistence alone was the justification for the regulation of PFASs as a class in California (Balan et al., 2021).

Further papers have discussed the role of persistence in decision making as the most important criterion or only property to justify regulation (Cousins et al., 2020b; Klöpffer, 1994; Mackay et al., 2014; Persson et al., 2013; Scheringer et al., 2022; Stephenson, 1977), see also Annex B.4.1.5.

### 1.1.4.3. Long range transport potential (LRTP)

The LRTP is assessed and discussed in more detail in Annex B.4.2.8. PFASs may concentrate in the respective compartment into which PFASs partition according to their specific properties (e.g. water-soluble substances concentrate in water, while volatile substances partition to air). PFASs can be transported by air, water and matrices to which they are adsorbed or absorbed, such as dust, sediments, migratory animals, or through matrices in which it is included as additive, e.g. polymers. Because of non-degradability, the movement of their carriers leads to global drift of PFASs over long distances from the point of release. Calculated characteristic travel distances (CTD) of FTOHs and PFCAs reach thousands of kilometres in air and water. Consequently, PFAS discharges from some regions could affect the whole earth, even remote areas like the Antarctic. For volatile PFASs, such as FTOH, the long-range transport route is expected to change from LRTP via air to water when the substances degrade to their corresponding arrowhead PFCAs. Transport pathways are generally complex, also for other precursor-PFASs due to the change of the fate-determining properties during degradation into their arrowheads. The residence time of a substance in a certain compartment may strongly vary and depending on the respective compartments moving capacity, the transport of PFASs to remote areas occurs time delayed.

As provided by monitoring data (see Annex B.4.2.7.) PFAS contamination is not geographically limited but PFASs are found ubiquitously in the environment. This is due to their wide dispersive uses and distribution in a global market but also due to their global distribution in long-range environmental transport from source regions to the entire global environment including remote areas.

### 1.1.4.4. Mobility

Generally, substances with a moderate to high solubility in water combined with a low adsorption potential can be considered to have a high mobility in the aqueous environment. Such substances tend to stay in the water phase, rather than bind to organic material and sediments.

Water solubility of PFASs varies from very soluble to insoluble (see examples in Annex B.1.2.). For example, the water solubility of PFCAs and PFSAs is high with carbon chain length below 8 but with increasing carbon chain length the solubility tends to decrease. Generally, short-chain PFAAs and many long-chain PFAAs can be considered mobile in water (see Annex B.4.2.1. for details). Degradation of precursor-PFASs in the environment to PFAAs also render the precursors mobile in water at some point of time. For example, fluorinated olefins, which are not necessarily all mobile themselves, degrade into PFCAs (see Annex B.4.1.3.) hence becoming mobile. The same occurs, e.g. to side-chain fluorinated polymers.

The adsorption potential of PFASs is also subject to variation depending on the PFAS (see details in Annex B.4.2.1.). Data for PFCAs, PFSAs and perfluoroalkylphosphonic acids indicate that there is a trend of increasing $K_{OC}$ values with increasing chain length (e.g. PFCAs $\log K_{OC}$ 0.437-3.3, PFSA 0.352-3.675). Perfluorinated olefins which lack a functional group have higher $K_{OC}$ values than the PFAAs with the same chain length. It is expected that PFASs lacking a functional group will be more adsorptive than a PFAS with a functional group of the same chain length. Ding et al. (2018) measured the partitioning behaviour of PFASs between the dissolved phase, surface sediment and suspended particulate matter in the Dalian Bay, China. PFOA, PFBA, and PFBS were the predominant PFASs in the water dissolved phase, while PFBS, PFOS and PFOA were the most prevalent compounds in suspended particulate matter. A log Kd for PFBS of 3.4 was reported, and it was concluded that PFSAs (including PFBS) and the long-chain PFCAs were more inclined to partition to the suspended particulate matter phase.

It should however be noted that up to a chain length of 4 carbons perfluoroalkanes have boiling points below 0 °C. It is more likely that these short-chain perfluoroalkanes evaporate into the air when released to the environment. The same applies to the short-chain perfluoroalkylethers without further functional groups (see Annex B.1.2.).

Measured data illustrating the distribution of PFASs in the environment is provided in Annex B.4.2.7. These are reflected by the property data on the mobility of PFASs.

Mobility of PFASs in water contributes to their long-range transport potential, drinking water contamination potential, uptake in plants and in combination with high persistence to increase of internal exposures in biota, see further discussion on mobility as a concern in Annex B.4.2.1. and the subsection 1.1.4.10 below.

For those PFASs, which are volatile (see Annex B.4.2.4.), distribution in the environment occurs mainly via air.

### 1.1.4.5. Accumulation in plants

A detailed assessment of accumulation in plants is provided in Annex B.4.4.

Studies on accumulation of PFASs in plants are lacking for the majority of PFASs. However, several studies provide evidence that plants accumulate many PFASs to levels which exceed the expected levels based on equilibrium partitioning. According to the review by Li et al. (2022), the reported average log Bioaccumulation factor (BAF) values range between 0 and 1 (or even exceed 1 for PFBA), indicating potential of PFASs to transfer from contaminated soil to plants. High accumulation of some PFASs is also indicated for instance in the study by Blaine et al. (2013), where the accumulation of PFCAs (C5-C10) and PFSAs (C4, C6, C7, C8, C10) was investigated in lettuce and tomato grown on biosolid-amended soils. The reported BAFs for lettuce in this study ranged between 0.19 – 28.4 (municipal soil), and between 0.52 – 56.8 (industrially impacted soil) (C10 PFSA < LOQ). The greatest accumulation was seen for C4 PFCA. Another study with plants from biosolid-amended fields (Yoo et al., 2011) reports the highest accumulation factor among all measured PFASs (PFCAs, PFSAs, FTOHs) for PFHxA, with a grass/soil accumulation factor of 3.8. Accumulation potential (BAF) decreased logarithmically with increasing chain length. It is noted that all the studied PFASs are arrowhead PFASs, hence also very persistent.

A recent review article on exposure routes, bioaccumulation and toxic effects of PFASs on plants shows that bioaccumulation processes of PFASs in plants are highly variable, because of the complexity of PFAS chemistry (Li et al., 2022).

Whereas short-chain PFASs typically accumulate in above-ground plant parts, long-chain PFASs accumulate in roots and show lower translocation factors to the above-ground plant parts. This is influenced by the higher water solubility, lower molecular size and lower hydrophobicity of the short-chain PFASs. Studies also indicate that the short-chain PFCAs are more effectively taken up by plants compared to the long-chain PFCAs (Felizeter et al., 2014; Yoo et al., 2011).

Consumption of plant material, e.g. grains and vegetables either as roots or above ground plant parts, function as a source of PFASs to humans and animals. Accumulation of many arrowhead PFASs in plants increases the relevance of this route of exposure. Accumulation in plants is of additional relevance when agricultural soil is contaminated with PFASs, leading to the contamination of agricultural plants (see Annex B.4.2.3. and Annex B.4.4. for an example case).

#### 1.1.4.6. Bioaccumulation

A detailed assessment of bioaccumulation of PFASs is provided in Annex B.4.2.9., while monitoring data also provide information on bioaccumulation in the field as outlined in Annex B.4.2.6. and Annex B.4.2.7. By now, C11-C14 PFCAs and C6-PFSA have been shown to fulfil the vB-criterion and C8-C10-PFCA the B criterion (vB not assessed) under REACH.

Studies with mammalian species show that PFASs are readily absorbed and distributed across various tissues and that some PFASs (particularly the long-chain PFASs) have a long half-life in organisms. Data for PFCAs and PFSAs and some PFECAs indicate that PFASs partition into proteins. Binding to albumin and transporter proteins, which are classes of proteins ubiquitously expressed, efficiently distributes PFASs into different tissues, and enhance passage across brain, placental barriers, and transfer via milk. Accordingly, PFASs do not follow typical accumulation patterns, i.e. partitioning into adipose tissue, but rather bind and accumulate in protein-rich organs like the liver.

Generally, Bioconcentration factor (BCF) measurements have been focused on PFHxS, PFOS, PFOA, PFNA, and PFDA. Accordingly, in general, carbonyl and sulfonyl PFAS classes are relatively data rich, whereas phosphate, fluorotelomer, and ether PFAS classes are data-limited for fish and lack data for most other taxonomic classes. Among the 43 PFASs for which mean BCF and BAF studies are available in different aquatic species 62% (27 compounds) have a BCF and/or BAF values above the threshold for fulfilment of the B-criterion in REACH Annex XIII. For example, PFASs such as F-53B and p-perfluorous nonenoxybenzenesulfonate (OBS) were recently shown to significantly accumulate in common carp (Shi et al., 2020; Shi et al., 2015). The existing studies suggest that PFPiAs and PFPAs follow similar patterns as PFCAs where the total number of perfluoroalkyl carbons correlate with the BCF. In a BCF study by Chen et al. (2016) the long-chain PFPiAs (total carbon ranged C12 to C18) would appear to exceed BCF of 5 000 in fish (whole-body log BCFs ranged between 4.6 and 9.2), while the log BCF values of the PFPAs (C6-C10) ranged between 1.2 and 2.3 (see further details in Annex B.4.2.9.).

Furthermore, PFASs, particularly the PFAA arrowheads, accumulate more in air-breathing organisms as compared to gill breathing organisms, because unlike the latter, air-breathers cannot readily eliminate PFASs by passive diffusion. Elimination to water via gills is facilitated by the appropriate solubility of most PFASs, while air-breathing organisms are not able to excrete PFASs by ventilation via the lungs to air. Thus, established assessment methods of bioaccumulation, based on bioconcentration testing in aquatic organisms, do not function as methodology for estimating the bioaccumulation behaviour of PFASs in general (see Annex B.4.2.9.5.). Unfortunately, in comparison with freshwater species, laboratory bioaccumulation data are very limited for air-breathers. Further discussion on toxicokinetic behaviour from experimental studies in laboratory mammals, is provided in Annex B.4.2.9.1. and Annex B.5.1.

Short-chain PFASs are generally more hydrophilic and mobile in aqueous systems than long-chain PFASs. Short-chain PFASs are also more readily excreted by urinary excretion in air-breathing organisms and tend to be less bioaccumulative, while the strength of bioaccumulation potential usually increases with perfluoroalkyl chain length. In general, BCFs and BAFs of PFASs with 8 or more carbons increase uniformly with increasing number of carbons in the alkyl chain, with highest bioaccumulation potential of compounds with 12 to 14 carbon-chain length. Available laboratory bioconcentration studies in freshwater fish indicate that PFASs with a shorter alkyl chain, i.e. HFPO-DA, EEA-NTH, ADONA, are generally less bioaccumulative in fish. However, bioconcentration factors below 2 000 L/kg could potentially reach similar levels in biota compared to substances that are known to bioaccumulate due to increasing and irreversible exposure to PFASs (see section 1.1.4.10/ Annex B.4.3.). Furthermore, the relationship between chemical structure, affinity to proteins and accumulation pattern is complex and still a matter of research. For example, a comparison of laboratory BCFs with field BAFs revealed that 60% (26 of 43 comparisons) of the BAFs are greater than their corresponding BCFs (Burkhard, 2021), possibly due to multiple exposure routes taking place in field conditions (e.g. exposure via food in addition to exposure from the water phase only).

Due to the aforementioned properties, many PFASs accumulate in air-breathers, and long-chain PFASs biomagnify in marine and fresh-water food webs, reaching high levels in top predators including humans and vulnerable species (see Annex B.4.2.9.6.). It is noted that as a consequence this may negatively affect the recommendations related to consumption of meat and/or entrails of certain animals (e.g. deer, fish for PFOS and PFOA in EFSA (2018)).

Field studies on long- and short-chain PFASs that can be analytically distinguished demonstrate that some PFASs (e.g. PFBA, PFBS, PFHpA, PFHxA, PFHxS, PFOS, FOSA, 6:2 FTOH, F-53B, TFA, and C9-C11 PFCAs) are found in various environmental compartments (Annex B.4.2.6. and Annex B.4.2.7.) while particularly PFOS and long-chained PFCAs are detected in elevated levels in mammals, birds, fish or other vertebrates throughout Europe and globally. Notable is that not just arrowheads but also precursors (e.g. 6:2 FTOH) are found in biota, even though only very few studies focus on their detection. Given the fact that for the majority of PFASs no, or insufficient, data on bioaccumulation behaviour are available, substantial and large uncertainties remain. Overall, the data on the bioaccumulation potential of PFASs, which are currently available, are not sufficient to substantiate bioaccumulation in the environment for all PFASs. It is noted that routine target analysis of food items and wildlife usually includes only the most commonly used and/or identified C4–C15 PFCAs and C4–C10 PFSAs, missing a large fraction of other PFASs as outlined in Annex B.4.2.6. Hence, the actual combined exposure to PFASs is expected to be even higher than observed in the monitoring programs.

Yet in conclusion, considering the increasing lines of evidence from modelling, laboratory and monitoring studies, there is a justified concern for a subset of PFASs being bioaccumulative while large uncertainties remain for the majority of compounds due to lack of data.

### 1.1.4.7. Ecotoxicity

There is evidence for a subset of PFASs that they cause adverse effects in ecotoxicological tests with various environmentally relevant species e.g. invertebrates, fish, amphibians, birds, reptiles, mammals, plants or wildlife (see Annex B.7.1. and Annex B.7.2.). Adverse effects occur on the molecular level (e.g. genotoxic effects), the organ-level (e.g. steatosis (fatty liver)) as well as organism level (e.g. mortality or reproduction) the latter of which may also have relevance at the population level. The large number of different substances with heterogenous properties (e.g. due to different functional groups) in the group of PFASs makes the assessment of their ecotoxicity very complex. Additionally, conventional ecotoxicological tests may not be suitable to detect long term effects from exposure to PFASs across several generations. Lastly, it is noted, that 6:2 FTOH was evaluated by RAC to warrant a classification of Aquatic Chronic 1 (ECHA, 2021b). A new study showed various strong ecotoxicological effects of PFOA and PFOS on earthworms (Delor et al., 2023).

### 1.1.4.8. Endocrine Activity/Endocrine Disruption

Collected evidence of endocrine activity (EA)/endocrine disruption (ED) of several PFASs indicates that adverse effects through interaction of certain PFASs with the hormone system as well as cross generational exposure cannot be excluded (see details in Annex B.7.5.). In summary, the data from *in silico*, *in vitro* and *in vivo* studies listed in Annex B.7.5. provide indications of interactions of certain PFASs with the endocrine system of environmental species. Adverse effects observed in those studies comprise e.g. altered receptor activity, changes of hormone levels, reduced fecundity, changes in sex-ratio, or developmental inhibition. Similar limitations apply to the assessment of EA/ED of PFASs as described above for the ecotoxicity of PFASs. Additionally, it should be mentioned that the substance evaluation (SEv) for 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctylacrylate (6:2 FTA) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2 FTMA) was recently concluded, stating that "Available studies indicate that 6:2-FTOH (one main degradation product of 6:2 FTA/6:2 FTMA) interacts with the HPG (hypothalamic-pituary-gonadal) axis and PFHxA (another important degradation product) interacts with the HPT (hypothalamic-pituary-thyroid) and HPG axis"[8].

### 1.1.4.9. Effects on human health

Available scientific literature on PFASs that have been investigated in animal and epidemiological studies clearly show human health hazards and concerns for many PFASs (for details, see Annex B.5.).

There is a vast amount of literature published on the health effects of PFASs, mostly on the PFAA arrowheads PFCAs and PFSAs, especially on PFOA and PFOS. Other PFASs have been less well-studied, but scientific attention and available hazard information is increasing. Some precursors to PFAAs may be of less direct concern with regard to human health effects, but will ultimately add to exposure of PFAAs due to degradation (see Annex B.4.1. for details) and hence, also indirectly add to the concern. Below, the human health effects reported for PFASs are summarized per main PFAS category.

PFAAs (arrowheads and precursors)

In humans, many PFAAs are readily absorbed after oral exposure, while less is known regarding absorption after inhalation and dermal exposure (details in Annex B.5.1.1.1.). Many PFAAs bind to proteins and are thus distributed to protein-rich tissues including liver, kidneys, and blood. PFAA precursors are metabolised in humans to arrowhead PFAAs, which are not further metabolised. Estimated human half-lives for PFAAs range from a few days to a month (e.g. PFBA, PFBS, PFHxA) to a couple of years (such as PFOA, PFNA, PFDA, PFHxS or PFOS) to over 10 years (e.g. PFUnDA). Half-lives are much shorter in rodents (and other experimental animal models) than in humans and a difference in half-lives between sexes is often observed. Consequently, the observed toxicity in rodents may underestimate the toxicity to humans. PFAAs are mainly excreted via urine and faeces and are released to the environment. Some PFAAs have a strong potential for bioaccumulation in humans as shown by the long half-lives (details in Annex B.5.1.1.4.) due to the protein-binding properties (details in Annex B.4.2.9.2.).

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[8] Once published, the conclusion document can be found here: https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ebe59, date of access: 2023-01-05.

EFSA extensively reviewed the epidemiological evidence for association between PFAS exposure and adverse effects in humans (EFSA, 2018; EFSA, 2020). Most data were related to PFOS and PFOA, but information was available also for some other PFCAs and PFSAs. EFSA inferred that there is sufficient evidence to conclude that there is an association between increased serum levels of various PFCAs and PFSAs and reduction in vaccine antibody response, increased serum cholesterol, increased serum alanine transferase (ALT) and reduced birth weight. EFSA also identified some evidence of increased propensity of infections (see Annex B.5.2.1.5. and Annex B.5.3.1.1.). The association with immune effects was the most sensitive endpoint in humans and was a sensitive endpoint also in experimental rodents. Based on this EFSA has established a Tolerable Weekly Intake (TWI) of 4.4 ng/kg bw/week for the sum of PFOA, PFOS, PFNA, and PFHxS (EFSA, 2020). Epidemiological studies published after the EFSA opinion generally support or strengthen conclusions on the above-mentioned associations and some more data on other PFAAs than PFOS and PFOA have become available (Annex B.5.3.1.1.). Furthermore, additional data for the PFOS alternative 6:2 Cl-PFESA (F-53B), which were not evaluated by EFSA, indicate similar associations with these health outcomes.

Experimental animal studies across different groups of PFAAs demonstrate that liver, kidney, thyroid, immune system, and reproduction are main targets of PFAAs' toxicity, as outlined in Annex B.5.2. In rodent studies, the most consistent effects included enlarged liver, hepatocellular hypertrophy, increased serum ALT, increased kidney weight, toxicity to reproduction, effects on lymphoid organs, and decreased serum thyroid hormone levels. In particular, liver effects have been observed for most PFAAs for which animal studies are available (Annex B.5.2.1.1.). For PFOS, PFHpA, PFOA, PFNA, and PFDA and their salts this has resulted in harmonized classifications for carcinogenicity (Carc. 2, except for PFHpA), reproductive toxicity (Repr. 1B), effects on or via lactation (Lact., except for PFHpA) and specific target organ toxicity - repeated exposure (STOT RE 1, except for PFDA), see Table B.2. in Annex B.3.1. Harmonized classification for 6:2 FTOH (STOT RE 2) has been agreed by RAC but is not yet officially included in Annex VI of CLP.

Data available for less well-studied PFAA arrowheads and some PFAA precursors indicate that these PFASs can have similar effects as the well-studied ones mentioned above (see Annex B.5.2.). For example, PFBA exposure of experimental animals resulted in similar effects on liver (enlarged liver, hepatocellular hypertrophy and partially necrosis) as well as thyroid hypertrophy and full litter resorption, although effects occur at higher doses compared to PFOS/PFOA. Another example is HFPO-DA, which was initially introduced as a safer alternative to PFOA but showed comparable concerns as PFOA (Blake et al., 2020) and for which US EPA recently proposed a lower reference dose than for PFOA and PFOS (EPA-US, 2021a).

As supporting evidence for similar toxicity concerns, a number of other PFAAs and PFAA precursors have self-classifications for Carc., Repr., Lact. and/or STOT RE. These self-classifications cover, for example, the following PFAS categories: the side chain aromatics (part of which are TFA precursors), the fluorotelomers (e.g. fluorotelomer alcohols, epoxides, (meth)acrylates, sulfonic acids, etc.), and other PFAA-precursors (e.g. perfluoroalkyl iodides, sulfonamides, carbonyl amides etc.; details in Annex B.3.2.). Exemplarily of note, HFPO-DA, POSF, 6:2 FTSA and 8:2 FTSA have self-classifications for STOT RE, and POSF as well for Repr. Even though there is still a large number of PFASs that have no (self-)classification for the properties of concern, the absence of classification does not mean that these PFASs do not have these properties. It is more likely that for the vast majority of these substances, no study data are available to serve as a basis for classification. In the absence of evidence to the contrary, it can therefore be assumed that some of the less well-studied PFAAs and PFAA precursors also exhibit one or more of the properties of concern.

Many PFASs contain only a single –$CF_3$ group and are considered potential TFA precursors as a special subclass of PFAAs. This group is heterogeneous with various types of effects and mechanisms of actions. The effects of these substances measurable in standard tests can often be attributed to the non-fluorinated parts of the substances. However, as most of these substances are expected to ultimately degrade in the environment to TFA (details in

Annex B.4.1.), they will contribute to the overall exposure to and risks of PFAAs. Concerns for human health by TFA itself are limited to effects at high doses in experimental animals: liver effects (increased liver weight, hepatocellular hypertrophy, increased ALT), increased kidney weight, decreased white blood cells, reduced weight of reproductive organs, litter loss, reduced body weight of offspring, and malformations (see Annex B.5.2.).

Oligomeric/polymeric PFASs

The Dossier Submitters identified oligomers as well as diverse groups of polymeric PFASs, such as side-chain fluorinated polymers, fluoropolymers, incl. fluoroelastomers, and perfluoropolyethers (details e.g. in Annex A.2.1.2. and Annex A.2.1.4.). Under the REACH regulation, oligomers are not defined. They are composed of a small number of linked monomer units but do not fulfil the criteria of the polymer definition in the REACH regulation (Article 3(5)). For polymers defined under REACH, no registration is required to date. No toxicity information was found in the REACH registered substance database for oligomeric or polymeric PFASs. Potential risks of polymers to human health are still under estimation (BIO by Deloitte, 2015; Bougas et al., 2020). Solid polymer particles (non-fluorinated and fluorinated) are partially restricted under REACH in the restriction for intentionally added microplastics (ECHA, 2019a; ECHA, 2020). The microplastics restriction discusses concerns related to synthetic polymer microparticles in general (ECHA, 2019a; ECHA, 2020), which may cover the concerns related to solid particles of polymeric PFASs. Some occupational studies showed effects of particles of polymeric PFASs (see Annex B.5.4.), but PFAS-specificity remains unclear.

Properties within the group of oligomeric/polymeric PFASs can vary considerably. Oligomers/polymers can vary in terms of molecular weight distribution, physical state, and possible inclusion of co-monomers and others, but can carry the same name and/or CAS number. Moreover, unique identifiers for oligomeric/polymeric PFASs are often not available which can further complicate clear assignment of the substance to health effects. Additives and non-intentionally added substances (NIAS) can also play a relevant role in the final oligomer/polymer product. For further details see Annex B.5.1.2. and ECETOC (2019). Furthermore, the end of life fate of the polymers is uncertain (Annex B.4.2.7.8.).

Only a few studies with toxicological information are available for this diverse group of oligomeric and polymeric PFASs. Most available toxicological studies of oligomeric/polymeric PFASs investigated oligomeric PCTFE oils and pure PCTFE oligomers.

Repeated oral and inhalation animal studies (mainly rodents) with oligomeric PCTFE oils as well as pure trimer and tetramer oligomers, reported adverse health effects such as liver and kidney effects as well as loss of body weight or reduced body weight gains, which would generally fit the typical effects observed for non-polymeric PFASs (details in Annex B.5.2.1.). The available data indicate that oligomeric PCTFE can be bioavailable.

For human inhalation, following occupational exposure to degradation products of polymeric PTFE (e.g. pyrolysis products) or particles (e.g. spray application), severe toxic lung effects are reported (details in Annex B.5.4.).

The structures of side-chain fluorinated polymers as well as perfluoropolyethers are different from that of fluoropolymers. Little to no data is available on the toxicity of these two groups of polymeric PFASs. Side-chain fluorinated polymers are considered potential PFAA precursors, as it is expected that they release PFAAs at any point in their lifecycle (details in Annex B.4.1.3.). For a polymeric PFPE product in one study, male rats showed mild degenerative change in the basophilic tubules of the kidney following oral exposure (Malinverno et al., 1996) (details in Annex B.5.2.1.3.).

Clarity on effects after repeated exposure of the diverse group of oligomeric/polymeric PFASs cannot be given on the basis of available data. However, given that at any point in their lifecycle oligomeric/polymeric PFASs may generate and/or release non-polymeric PFASs, e.g. PFAAs, in particular at end-of life (Lohmann et al., 2020), oligomeric/polymeric PFASs contribute to the overall exposure to and risks of non-polymeric PFASs.

Fluorinated gases

For fluorinated gases, some effects are similar to those observed for PFCAs and other PFAA arrowheads, in particular effects on liver of some HFCs, HFOs and HFEs and effects on lymphoid organs of some HFCs and HFOs (see Annex B.5.2.1.). Available data indicate that most of the fluorinated gases have lower potencies compared to the arrowheads. Moreover, some fluorinated gases (e.g. some HFOs) ultimately degrade to PFAAs, e.g. TFA or PFBA (Annex B.4.1.3.2.). Hence, also these gases will contribute to the overall exposure to and risks of PFAAs.

Combined effects of co-occurring PFASs

Many different PFASs co-occur in the environment, drinking water, food, and in human blood (see Annexes B.4.2.6., B.4.2.7., B.9.7., B.9.29., B.9.30.). Thus, there is combined exposure to multiple PFASs, many of which exhibit similar effects, such as effects on the liver, kidney, thyroid, serum lipids, and immune system. Accordingly, an assessment of hazards and risks taking into account such combined exposure would reflect more realistic exposure conditions than single compound assessments.

The similarity of the effects of most PFAS groups, often targeting the same organs, raises concerns about cumulative effects of PFASs (Annex B.5.5.). The lack of toxicity data for most PFASs precludes precise modelling of combined effects of all PFASs but concentration addition has been suggested as a precautious first tier, irrespective of the modes/mechanisms of action of the mixture components (Backhaus and Faust, 2012). This may give a realistic worst case estimation of combined toxicities for risk assessment procedures even if similarity of components is unknown (Backhaus et al., 2000; Martin et al., 2021). Dose addition has also been adopted as the default assessment approach in EFSA's "Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals" (EFSA, 2019).

However, due to the immense number of PFASs and the lack of toxicological data for the vast majority of them, a combined assessment for all PFASs is unattainable within the scope of this restriction proposal. In conclusion, it is emphasized at this point that combined exposure to different PFASs affecting the same target organs may result in combined additive effects rendering exceedance of effect thresholds or limit values more likely than assessment of individual substances.

Conclusion on human health effects/concerns

In conclusion, for the majority of the PFAA arrowheads identified (and many of their precursors) there is reasoned concern for long-term human health hazards especially with continuously increasing exposure due to ongoing emissions, persistence, mobility and/or bioaccumulation. Despite different potencies of different substances, overall effect patterns are similar for a variety of PFASs, especially arrowhead substances. Additionally, co-occurrence of PFASs leads to combined exposure and raises concerns of potential combined effects.

Considering the increasing lines of evidence for effects of well-studied PFASs occurring at lower levels than previously anticipated (EFSA, 2020), the human exposure to the combination of the four PFASs PFOA, PFNA, PFHxS, and PFOS already exceeds the existing limit value established by EFSA. Also recent human biomonitoring data on PFAS from the HBM4EU program confirm that PFAS exposure is too high and may result in a human health risk (Bil et al. (2023); see also Annex B.9.30.2.). Furthermore, remediation/decontamination of PFASs from the environment and drinking water is insufficient with current conventional and advanced treatment methods (see Annex B.4.5.). Hence, any additional exposure to other PFASs can add to the overall toxicity potential in the future. Exposure therefore needs to be minimised.

### 1.1.4.10. Concerns triggered by combinations of properties

Most of the PFASs manufactured, used and released to the environment can be expected to have several of the above listed properties of concern (i.e. LRTP, mobility, etc.), depending on the specific identity of the PFAS. Confirmation of these properties of concern through scientific studies is only available for a few, well-studied, PFASs. A combination of at least two or more properties is expected in particular for the arrowhead PFASs (see more details in Annexes B.1.2., B.4., B.5. and B.7.). As explained above, all arrowhead PFASs are very persistent, and their precursors will contribute to the environmental concentrations of the arrowheads as well through degradation in the environment. The presence of some of the additional properties is expected to correlate with each other: these are mobility in water with enrichment in plants and LRTP, volatility with global warming, volatility with LRTP.

In the following sections the concerns triggered by certain combinations of PFAS properties are discussed.

<u>High potential for ubiquitous, increasing and irreversible exposure of the environment and humans</u>

Although exceptions may occur, the overall assumption is, that the more time that passes after the release of PFASs into the environment, the more the environment is exposed to those PFASs which are the most mobile in water and/or the most volatile and most persistent among the PFASs. This is based on the general knowledge on degradation pathways and, more specifically, the observations from monitoring data, model data, degradation testing (see Annex B.4.1. for details) and information on mobility (Annex B.4.2.1.) and volatility (Annex B.4.2.4.).

Very persistent properties in combination with mobility in the aquatic environment results in a scenario where none of the environmental compartments act as a potential removal pathway (i.e. a sink). In this scenario, mobility increases the already high potential of very persistent substances to result in exposures of biota and humans. Marine surface water is an important compartment for very persistent and mobile PFASs and facilitates their distribution by advection (Cai et al., 2012). Occurrence of elevated concentrations of PFASs in waters near the points of releases are problematic, because mobile substances are also bioavailable for efficient uptake in the food chain. Cai et al. (2012) discuss this for coastal waters as an intermittent storage before PFASs are further diluted in the marine environment.

The very persistent PFASs have time to be distributed in and between environmental compartments, such as aquatic and atmospheric media. Combined with mobility, the distribution and transport via aqueous media is efficient and faster than for non-mobile substances. PFASs therefore reach effectively all media, including groundwater aquifers which function as drinking water reservoirs. This is illustrated by monitoring data showing that measured PFASs are already ubiquitously present in the environment (see Annexes B.4.2.6. and B.4.2.7.).

Furthermore, PFASs are subject to long-range transport. Long-range transport in combination with very high persistence means that even the most remote sites of the globe and most vulnerable environments cannot be protected from PFASs exposures.

For the very persistent PFASs, environmental concentrations increase as a result of releases until reaching a steady state at a time in the distant future. In consequence also PFASs having less or no bioaccumulative properties can show elevated levels in biota as illustrated by monitoring data (Annex B.4.2.6.). Recent models demonstrate that mobile and persistent PFASs will ultimately reach over time—unless the exposure is removed—such high levels in organisms that they will affect both ecosystems and human health widely (Crookes and Fisk (2018)). The report by Crookes and Fisk (2018) indicates that also substances which have bioconcentration factors below 2 000 L/kg could potentially reach similar levels in biota compared to substances fulfilling the B or the vB criterion , provided that they are sufficiently persistent and mobile in the environment. For example, calculations in the study show that a substance with a half-life of 365 days and a BCF of 800 L/kg may reach comparable concentrations in a system as a substance with a half-life of 60 days and a BCF of 5 000 L/kg, if time allows for steady state to be reached, see Annex B.4.3. for further details.

As a case study applying the model of Crookes and Fisk (2018), the nominal biota concentration calculations were repeated for PFBS and compared with some relevant model substances {ECHA, 2019 #210}. A degradation half-life in water of 10 years for PFBS was assumed, representing a best-guess estimate in the absence of any measured degradation half-life, and the calculations were performed with the following bioaccumulation values: BCF fish: 23.5 (Chen et al., 2016); BAF crab 110 (Naile et al., 2013) and BAF fish 1 736 (Campo et al., 2015). The outcome of the modelling of development of biota concentrations for PFBS over time is shown in Figure 5. The model substances (A, B, C and D) have combinations of half-life and BCF as shown in Figure 5. An assumption in the model is that the substance is mobile and not removed from the aqueous phase so that the concentration, and therefore the exposure, is maintained unchanged over time.

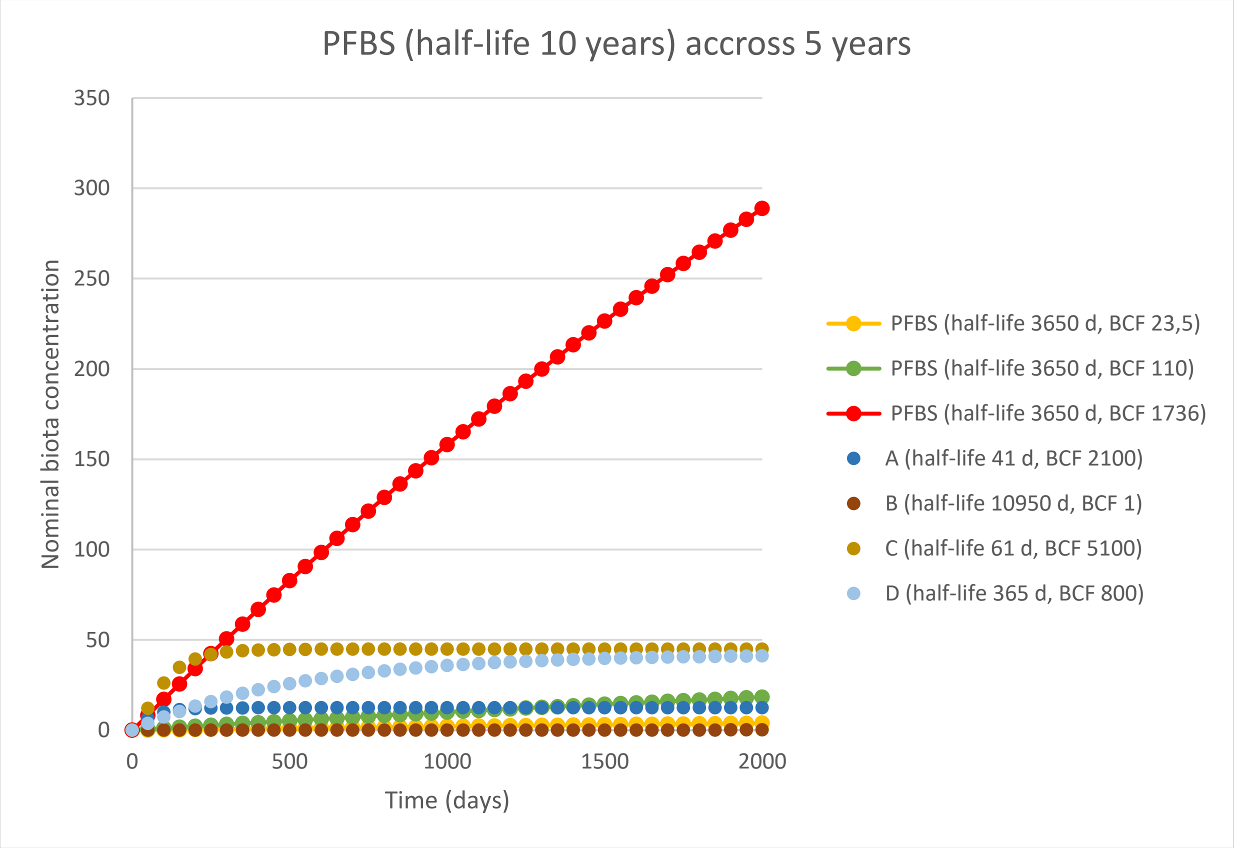

**Figure 5. Modelling of development of nominal biota concentrations for PFBS over time.**

Figure 5 demonstrates in a simplified way that when considering an appropriate long time scale, e.g. few decades (note Figure 5 shows only 5.5 years), a long degradation half-life for a substance may lead to high steady-state concentrations in biota, even when the BCF is only moderate. The green line represents a BAF of 110 measured in crab (Naile et al., 2013). The graph shows that this moderate BAF in combination with a half-life of 10 years, may lead to very high concentrations in biota over time. The green line even crosses the dark blue line, representing a substance with half-life in water of 41 days and a BCF of 2 100, i.e. a substance just exceeding the P and B criteria in REACH Annex XIII. For the substance B combination of BCF of 1 and half-life of 30 years the high steady state would be reached very slowly far beyond the time-scale of the simulation. When the model from the Crookes and Fisk (2018) report is used for PFASs, concentrations of very persistent and mobile subgroups in biota may be expected to exceed the biota concentrations for a persistent and bioaccumulative substance over time. The steady state in biota would only be reached for PFASs in the model in far future.

Bioaccumulation and mobility can be seen as properties facilitating exposure and enhancing the likelihood of adverse effects in particular when combined with the very persistent property. Regarding bioaccumulation this is due to the slowly reversible internal exposure caused by slow elimination kinetics in organisms and therefore elevated internal levels. Exposure to very persistent and mobile PFASs occurs continuously via drinking water and food crops. Finally, some PFASs (e.g. PFOA) can be both, mobile and bioaccumulative and distinguishing between the impacts of each of the properties to the observed levels is not always possible.

To conclude, mobility in combination with very high persistence cause a high potential for increasing contamination of surface waters and aquifers. This contamination is very difficult to reverse. Even if releases are ceased, the exposure levels of the arrowhead PFASs continue to increase until the precursor PFASs have gradually all vanished from the environment. The environmental stock of the arrowhead PFASs formed is expected to prevail in the environment for decades if not centuries and is readily available for uptake by biota and humans.

Difficulty to decontaminate water and to reduce emissions with site-specific risk management

The combination of the very high persistence of PFASs and mobility and for many PFASs also of surface activity trigger specific challenges to wastewater treatment and decontamination of, e.g. intake water used for drinking water production and contaminated sites (e.g. groundwater contamination around airports, see Annex B.4.5.).

Municipal sewage treatment plants are not able to remove very persistent and mobile PFASs as they remain in the water phase and cannot be degraded by the available micro-organisms within the retention time. The available chemical removal methods are expected to reach removal of only a small fraction from the aqueous phase. The suspended PFASs, however, cannot be degraded in sludge, or are in an ideal case merely degraded from precursor forms towards arrowhead forms. The monitoring data in influents and effluents of municipal sewage treatment plants supports this pattern (see Annex B.4.2.7.).

Conventional and advanced intake water treatment methods applied to produce process water for industry and drinking water are unable to effectively remove PFASs due to their persistence and inertness to chemical and thermal reaction. Thermolysis and sonolysis might achieve complete mineralization but come with high process costs. Other treatment processes cannot remove PFCAs and PFSAs. The same applies to PFECAs. Conventional adsorption, ion-exchange, and membrane filtration can remove long-chain PFASs, but are less effective for the more hydrophilic short-chain PFASs, see Annex B.4.5. for details.

Raw water used for production of drinking water is obtained either from groundwater, bank filtration or surface waters. Monitoring data already reveal a contamination of either drinking water itself or raw water, ground water and riverbank filtrates used for the preparation of drinking water (see Annex B.4.2.7.). A recent review paper from Li et al. (2020) on drinking water treatment concludes that short-chain PFASs are more widely detected, also persistent and even more mobile in aquatic systems, and thus may pose broader risks on the human and ecosystem health as compared to their long-chain counterparts. Routine target analysis, however, usually only addresses very few PFASs and thus misses a large fraction of total PFASs.

To conclude, there are significant limitations to remove the PFASs from raw water and wastewater or sludge. In general, it seems that releases to water cannot be mitigated with on-site removal techniques, although some specific exceptions may apply. Exposure of humans via drinking water cannot be prevented effectively. Removal or remediation might only be feasible for contamination hotspots in few specific cases, but not for the majority of the environment, such as large aquifers, surface waters and the world's oceans.

High potential for human exposure via food and drinking water

Accumulation of many PFASs in edible plants, the bioaccumulation potential observed for some PFASs in fishery products (and other products) and the very high persistence and mobility as discussed above, indicates human exposure via food. Furthermore, drinking water is also a source of PFAS exposures due to the difficulty to decontaminate intake water used for production of drinking water. The exposure via drinking water and food is expected to increase in future due to expected increasing concentrations of the arrowhead PFASs in the environment unless releases of PFASs are ceased. Even then it will take a very long time until the environmental concentrations are considerably reduced due to the high persistence of the substances. To conclude, the abovementioned combined properties of PFASs induce a high potential for exposure of the human population at large. Current exposure of the general population can be observed from the available biomonitoring data (see Annexes B.9.29. and B.9.30.).

Potential for intergenerational effects and delay of effects

Several PFASs are transferred to the offspring (see Annexes B.4.2.9.1. and B.5.1.). The high potential for human exposures and the expected increasing and irreversible exposures, as discussed above, in combination with the intergenerational transfer of PFASs indicate that none of the stages of human life and wildlife can be effectively protected from exposure to PFASs. The very long-term exposures, continuing over decades or even centuries increase the likelihood for intergenerational effects. Furthermore, although effects would not be yet observed, the expected increase of exposures to the arrowhead PFASs even after releases have been ceased, together with the above discussed results from tests on human health toxicity and endocrine disruptive effects, raise the likelihood of effects to be observed at a later stage. At such point of time the effects would be very difficult, and most likely impossible, to reverse.

Considering the increasing lines of evidence for effects of well-studied PFASs occurring at lower levels than previously anticipated (EFSA, 2020), combined with increasing findings of hazardous properties of less well-studied PFASs (e.g. (ECHA, 2021a)) and the increasing stock pollution and the expected irreversible ubiquitous environmental contamination, as outlined above, indicates a threat of irreversible damage for future generations. The findings from studies investigating endocrine effects (see section 1.1.4.8 and Annex B.7.5.) add to the concern. If yet unidentified adverse effects do occur these cannot be reversed.

Potential for causing serious effects although those would not be observed in standard tests

Already only the arrowhead PFASs constitute a diverse mixture of exposure whereas all the released PFASs in combination with the arrowhead PFASs form a very complex cocktail in the environment. As concluded in Annex B.5.5., combined effects should not be excluded but rather expected in this situation. There are no standard tests available which could simulate the exposure of PFASs taking place in the real environment. Additionally, potential effects arising from low-dose long-term exposure, as well as multigenerational exposures cannot be appropriately addressed by standard tests.

Additionally, the fact that exposures may take place at a different location than where releases occurred, and at a different moment in time due to the persistence, impedes the understanding of potential effects taking place.

Estimation of future exposure levels and safe concentration limits is highly uncertain

Currently no appropriate tools exist to predict future exposures reliably. The prediction is further complicated for PFASs by the degradation of the precursors to the arrowhead PFASs. Thus, it can be expected that the total amount of arrowhead PFASs present in the environment at the same time is even higher than the amount of arrowhead PFASs produced and used. The environment is also exposed to intermittent degradation products. For example, side-chain fluorinated polymers, which degrade in the environment at a very slow rate, are a long-lasting constant source for arrowhead PFASs especially if long timeframes are investigated for emissions and exposures over centuries. This applies particularly to the end of service-life where surface soils and landfills constitute a major global reservoir for PFASs (Washington et al., 2019). One study demonstrates how the stock of arrowhead precursors at a contaminated site will remain a source of PFAS emissions (i.e. PFBS and PFHxS) for centuries (Ruyle et al., 2023).

Currently it is also not possible to reliably assess (eco)toxicity of all PFASs. This is on the one hand reflected by the increasing lines of evidence for effects of well-studied PFASs occurring at lower levels than previously anticipated (EFSA, 2020), findings for less studied PFASs (ECHA, 2021a), and the lack of (eco)toxicity data for the vast majority of PFASs. On the other hand, the prediction of safe levels is more challenging, if not impossible, due to the complex mixture of used PFASs prevailing in the environment over long-term. The simultaneous exposure to the transient degradation products of the precursors impedes such a prediction before they finally form their respective arrowhead substances. As pointed out in Annexes B.5. and B.7. on effects to human health and ecotoxicity, both similar effects and different types of effects have been observed in available data across the PFASs. Combined effects can be expected over the long-term increasing exposure periods, as described in Annex B.5.5. This furthermore complicates the derivation of safe levels.

Global warming potential

Some of the PFASs are persistent and volatile and will partition to the atmosphere where they will stay for a very long time. These PFASs may have a considerable global warming potential which could contribute to global warming. In fact, some of the strongest greenhouse gases known are PFASs, for details see Annex B.7.3.

One of the most relevant subclasses of PFASs that contribute to global warming are the fluorinated gases, e.g. hydrofluorocarbons (HFCs), hydrofluoroolefins (HFOs) and hydrofluoroethers (HFEs). Emitted gases reside in the atmosphere, and eventually, they will degrade over a shorter or longer timeframe and the contribution to global warming will be removed, e.g. via formation of TFA that precipitates with rain or other substances like HF and $CO_2$. However, also other PFAS subgroups are volatile and contribute to global warming while they reside in the atmosphere (Oltersdorf et al., 2021).

## 1.1.5. **Exposure assessment**

### 1.1.5.1. Emission to the environment

Emissions of PFASs are, in combination with the environmental fate of persistent substances and/or the persistence of degradation products, the driver of the increasing PFAS pollution burden in the environment. The very persistent nature of PFASs results in a long-term, possibly infinite potential for environmental exposure and, hence, negative impacts to ecosystems and humans, once emitted. The high mobility of certain (groups of) PFASs allows for long-distance transport via air or surface water and ground water on a global scale ((Brase et al., 2021); see also section 1.1.4.3).

Emissions occur during PFAS production and processing, in product manufacturing (PFAS application in form of substances, mixtures and articles), in the use phase and in the end of life phase, See also Table 4, section 1.3.1 and Annex B.9. for specific information on emissions. Environmental emissions also depend on the rate of environmental release of PFASs. This depends on the physical state of the PFAS: Emissions of fluorinated gases are fast and direct, while emissions from solid PFASs (e.g. polymers) can span over long periods of time (i.e. decades or even centuries). The PFAS application (i.e. open or closed) also determines the speed of environmental release. For ski wax or consumer mixtures the release is quick. For side-chain fluorinated polymers, in e.g. textiles, the release is slower (mainly during washing and wear and tear). For durable applications, e.g. PFAS applications in electronics and automotive, the environmental release is very slow in the use phase and most of the PFAS load enters the waste stage.

For PFASs in durable articles like painted/coated articles, construction materials, electronics, solar panels, etc. there is a long use phase in between production and waste stage. These articles are a potential long-term source of emissions to the environment e.g. through wear and tear. PFASs in products that are not emitted during the use phase, will eventually enter the waste stage. In the waste phase additional PFAS emissions are to be expected. The amount of PFASs emitted during the waste phase depends on the waste (pre-)treatment method, e.g. recycling/re-use, landfilling and incineration (EPA-US, 2020; Stoiber et al., 2020).

Significant amounts of PFASs are stored in "technical stock", meaning there is a significant amount of PFASs that can potentially be released from products that are in use or on shelf, but will ultimately reach the end of life phase. Also in the waste stage, especially in landfills, "environmental stock" is present because of build-up of PFASs over time. Especially for highly persistent pollutants, stock pollution is a relevant problem as the environmental stock will grow over time, mainly from emissions from technical stock of long-lived products, both in the use and waste phase. Therefore, even with a full PFAS restriction in place, due to prolonged article use, recycling of old materials, and slow release of PFASs from landfills, emissions of PFASs and their arrowheads will continue for a long period even if a full ban is in place.

Emission calculations are predominantly based on the yearly PFAS tonnage brought to the EEA market. These include emissions from the waste phase for the presented uses (compare Annex A.3.). The approach to calculating waste stage emissions is described in Annex B.9.18. For some uses, specific emission factors could be derived based on stakeholder input and/or literature, but for the majority of uses ECHA's Environmental Release Categories (ERCs) are used because of the lack of industry specific data (see section 2.4.3 and Annex B.9.). ERCs describe the broad conditions of use from the environmental perspective, considering also default assumptions about the service-life of uses or applications. Emissions were assessed for the environment as a whole (one-compartment model), based on the aggregation of emissions across individual compartments (air, water, soil). Thus, the RMMs and OCs they are based on are not explained in detail here. Specific RMMs and OCs that were considered in the different PFAS life cycle stages are mentioned separately in the following sections.

Finally, PFASs may also be formed as by-products in other processes (e.g. aluminium processing (EPA-US, 2019; Marks et al., 2016)). Emissions coming from these kinds of processes where PFASs themselves are not used or placed on the market are not considered in this background document, just as other possible sources of uncontrolled PFAS emissions, e.g. as result of (factory) fires, uncontrolled landfill fires, as these fall outside the scope of the EU REACH regulation.

### 1.1.5.2. Emissions from PFASs manufacture

Information from stakeholders and literature reviews give insights into the presence and locations of the most important manufacturers/suppliers of PFASs in Europe. Based on information from stakeholders in the 2023 Annex XV consultation, twelve PFAS manufacturing sites in the EEA were identified (see Annex A.2.1.).

The Industrial Emissions Directive and European Pollutant Release and Transfer Register (E-PRTR) provide information about industrial point source emissions but information on PFAS emissions is very scarce and limited to a few fluorinated gases. No specific data was obtained for emissions from PFAS processors (e.g. drying, granulating), see Annex B.9.2. for further details. Besides direct emissions from manufacturing of PFAS, it should be noted that indirect emissions via waste from manufacturing can also occur. This was for example shown at the Chemours site in the Netherlands where indirect PFAS emissions via waste were investigated by the Dutch authorities (ILT, 2018; Tweede Kamer, 2019). Emissions from fluoropolymer manufacturing sites based on publicly available information like emission databases and emission permits were published by Dalmijn et al. (2024).

Based on input from the call for evidence, the 2nd stakeholder consultation and the Annex XV report consultation, several RMMs and OCs were reported, which are used to reduce the emissions during PFAS production. These are listed below:

Water and wastewater emissions:

- Physical separation
- Chemical precipitation
- Stripping
- Filtration
- Ion exchange
- Granular activated carbon

Air emissions:

- Caustic scrubber
- Granular activated carbon
- Regenerative thermal oxidation

Volatile Organic Compounds (VOC) emissions:

- Filtration
- Caustic scrubber
- Granular activated carbon
- Regerative thermal oxidation

Dust (solid particles) emissions:

- Filtration

PFAS polymerization aids emissions:

- Incineration
- Specific recovery/recycling techniques (with rates over 98%)

Further information can be found in Annex B.9.2.4.

Several studies indicate high numbers of processing aids emitted from fluoropolymer plants going into rivers or the surrounding air. Concentrations of PFASs in surface water sampling sites near known PFAS point sources such as upstream and downstream fluorochemical production plants (mainly fluoropolymer production) near Dordrecht/Netherlands and at the Alz and Ruhr River in Germany show considerable concentration differences for PFAAS and PFECA (Table B.140 in Appendix B.4.2.1.3). However, in recent years, emissions from manufacturing sites have been reduced significantly. With regard to fluorinated processing aids reductions of 99% to 99.99% compared to the 1990s are mentioned (Ameduri et al., 2023). These reductions have been mainly due to stricter emission conditions in permits.

Besides manufacturing, the processing of PFAS also can lead to emissions. There is evidence that the drying step (sintering) of fluoropolymers has led to substantial emissions of processing aids to air leading to the pollution of the air, and, as a result of atmospheric deposition, of the soil in Bavaria/Germany for instance (see Annex B.7.6.). Hence, it can be inferred that current RMMs and OCs are not sufficient to control PFAS emissions.

In some cases, also specific emission factors were reported by stakeholders that were calculated based on the RMMs and OCs in place. Relevant information by stakeholders was used to calculate emissions from PFAS manufacturing.

### 1.1.5.3. Emissions from article production and mixture formulation

Factories that process PFASs and apply PFAS-containing articles in products (i.e. production/formulation sites, metal finishing and surface treatment plants, textile industries, formulation of mixtures like paints, coatings, impregnation fluids, production of plastics, etc.) contribute to PFAS point source emissions. Many more facilities and sites are involved in PFAS processing than in PFAS production. In the EEA, there are for instance over 61 000 installations that may emit C6 fluorochemicals and polymers containing C6 side-chains (ECHA, 2019c; Goldenman et al., 2019). If all uses mentioned in Table 2 in section 1.3.1 are included, it is to be expected that there could be over 100 000 possible PFAS point sources from production and formulation alone in the EEA (estimate from EC (2020a)) with activities not concentrated in a few Member States, but spread throughout the whole EEA (Goldenman et al., 2019).

However, hardly any information on actual emissions from the PFAS processing industry has been found. In Flanders, PFAS processing industry (galvanic industry, textile industry, paint industry and paper industry) was studied (OVAM, 2018). Environmental monitoring data show elevated concentrations in matrices (soil, surface water, ground water) near sites where activities involving PFASs take place (see Annexes B.4.2.6 and B.4.2.7 on environmental monitoring data).

Application of fluoropolymer coatings, an important PFAS application method in many sectors, could lead to emissions from production sites (Langberg et al., 2021). Although processes are likely closed, some PFAS (micropowder) emissions might occur that are not accounted for in ERCs. Based on US permit information, in PFAS paste extrusion lines, printing lines, melt extrusion lines and fuse lines there is potential to generate toxic thermal PFAS decomposition products. Emissions are not quantifiable as they are highly variable due to variations in e.g. oven temperature and line speed. But emissions are likely. Therefore, the emissions calculated for production using ERCs might be an underestimation.

During the call for evidence and the 2nd stakeholder consultation, the amount of information received on emissions related to article production and mixture formulation was very limited. This also includes information on both RMMs and OCs. More information on RMMs and OCs was brought forward in the Annex XV consultation. The following RMMs and OCs for article production and mixture formulation were typically mentioned to be used (for comment IDs please see the respective sections in Annex B):

- abatement systems (e.g. scrubbers or filters)
- controlled conditions
- closed systems
- clean room environments
- advanced wastewater treatment systems
- regular trainings according to the national legal requirements
- specific risk management programs like Operation Clean Sweep
- requirements according to existing European legislation, e.g. Industrial Emissions Directive 2010/75/EU, General Product Safety Directive 2001/95/EC, F-Gas Regulation 2024/573/EU (now revised)
- Work according to standards such as ISO 9001, ISO 14001, ISO 45001

The above-mentioned measures seem to be already in place in many companies producing articles for the various uses assessed in the Background Document. It is unclear to the Dossier Submitters which share of companies have implemented these RMMs, due to existing legislation already in place for the reduction of emissions the share is assumed to be high though.

### 1.1.5.4. Product use emissions

PFAS emissions from the use phase occur both as point source emissions and as diffuse emissions. Diffuse emissions mainly result from wide-dispersive and widespread professional uses and from consumer uses of PFAS-containing products e.g. via wear and tear or improper use. Diffuse emissions are harder to control than point source emissions. Examples of these widespread and wide-dispersive uses are use (including washing) of treated textiles, use (including wear and tear) of impregnated building and construction materials, use of ski wax, use of paints and lubricants under uncontrolled conditions, use of cosmetics, use of cookware, use of PFAS-containing machinery etc. These types of uses result in direct emissions to the environment or indirect emissions, e.g. by run-off and discharge to sewage systems and subsequent discharge to surface waters by WWTPs.

The production and use emissions are presented in Table 1. For emissions related to the use of PFAS-containing articles, literature data were available for some applications (e.g. partly on food contact material).

For fluoropolymers, stakeholders oftentimes state that exposure and emissions during the use phase are negligible due to their stability and the conditions of use (e.g. ambient temperatures, encasement in housing, industrial settings, etc.). Thus, emissions are only possible due to abrasion, e.g. comment IDs #4432, 6293, 6520, 6791, 6808, 8269, 8375, 8389, 8695, 8714, 8951. Other stakeholders inform that emissions cannot be completely excluded and can occur as a result of improper handling, possible leakages, or degradation of the material during use, but are considered minimal (e.g. comment ID #8714). Stakeholders also inform that legal standards "partly require the use of fluoropolymers and fluoroelastomers, such as the EN 1514 series of standards and ASME B16.21 and 16.21 for flange gaskets" (e.g. comment ID 6774). Another stakeholder mentioned that their supplier stated that no protective measures need to be taken when coated metal products and solid components made of fluoropolymers or fluoroelastomers are used as intended. However, as such, PFAS articles in general and mixtures for consumer uses do not come with specific guidelines on RMMs and OCs.

For most uses in Table 1, ECHA ERC factors (ECHA, 2015) have been used to calculate PFAS emissions, although in some cases more specific emission factors were available (e.g. for paper and board food contact materials). Emissions of the specific group of PFASs in Table 1 refer to their respective emissions, e.g. polymeric PFAS emissions represent emissions of polymeric PFASs and not any other kind of PFASs. Important to note here is that emissions from side-chain fluorinated polymers are represented in the PFAS species group of PFAAs and PFAA precursors, instead of polymeric PFASs. This is because fluorinated side-chains are expected to follow the same reactivity pattern as PFAAs and PFAA precursors, see Annex B.4.1. In most cases the emission calculation is based on ERCs as no specific emission data was available.

**Table 1. Estimated annual emissions from the use phase for PFAS manufacture and major PFAS use sectors in 2020 (low, mid and high estimates)[a]. Emissions relate to production and use of new products on the market, unless stated otherwise. Mid points are used in impact assessment.**

| **Application** | **PFAAs and PFAA precursors [t/y]** | | | **Fluorinated gases [t/y]** | | | **Polymeric PFASs [t/y]** | | | **Total PFASs[a] [t/y]** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Low | Mid | High | Low | Mid | High | Low | Mid | High | Low | Mid | High |
| Manufacture[b] | 297 | 473 | 649 | 28 | 46 | 64 | 139 | 235 | 331 | **464** | **754** | **1 044** |
| TULAC[c] | 1 715 | 5 553 | 9 390 | | | | 2 659 | 5 092 | 7 526 | **4 375** | **10 646** | **16 917** |
| Food contact materials and packaging | 115 | 404 | 692 | | | | 180 | 197 | 214 | **295** | **600** | **906** |
| Metal plating and manufacture of metal products[d] | 0.08 | 31 | 61 | | | | 1.28 | 2.12 | 2.96 | **1.4** | **33** | **64** |
| Consumer mixtures and miscellaneous consumer articles | | | | | | | 1.6 | 9.14 | 16.46 | **21.6** | **29.1** | **36.5** |
| Cosmetics[e] | 0.12 | 0.12 | 0.12 | | | | | | | **0.14** | **32.2** | **64.3** |
| Ski wax | | | | | | | | | | **0.9** | **0.9** | **0.9** |
| Applications of fluorinated gases[f] | | | | *30 586*<br>1 642 | *30 586*<br>1 642 | *30 586*<br>1 642 | | | | ***30 586***<br>**1 642** | ***30 586***<br>**1 642** | ***30 586***<br>**1 642** |
| Medical devices | 402 | 402 | 402 | | | | 1 627 | 3 840 | 6 052 | **2 029** | **4 242** | **6 454** |
| Transport[f] | 0.2 | 0.5 | 0.8 | *15 359* | *15 359* | *15 359* | 239 | 453 | 666 | ***15 597*** | ***15 806*** | ***16 015*** |
| Electronics and semiconductors | 7.3 | 8.8 | 10.3 | 13.4 | 247 | 481 | 79 | 240 | 401 | **99** | **496** | **893** |
| Energy sector | 42 | 42 | 42 | | | | 53 | 134 | 219 | **95** | **178** | **260** |
| Construction products | 91 | 213 | 335 | | | | 1 454 | 3 369 | 5 284 | **1 546** | **3 581** | **5 618** |
| Lubricants | 25 | 26 | 26 | 3 | 3 | 3 | 984 | 1 558 | 2 132 | **1 013** | **1 587** | **2 161** |
| Petroleum and mining[d] | | | | | | | | | | **1.1** | **1.6** | **2.1** |
| Printing applications | | | | | | | | | | **1.5** | **8.6** | **15.7** |
| Sealing applications | | | | | | | 345 | 392 | 439 | **345** | **392** | **439** |

| **Application** | **PFAAs and PFAA precursors [t/y]** | | | **Fluorinated gases [t/y]** | | | **Polymeric PFASs [t/y]** | | | **Total PFASs[a] [t/y]** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Low | Mid | High | Low | Mid | High | Low | Mid | High | Low | Mid | High |
| Machinery applications | | | | | | | 5.6 | 17.7 | 29.8 | **5.6** | **17.7** | **29.8** |
| Other medical applications | <<0.01 | | 0.1 | 840 | 3 420 | 6 000 | 1 | 1.5 | 2 | **841** | **3 422** | **6 002** |
| Military Applications[g] | | | | 194.6 | 197.5 | 200.4 | 60.6 | 83.4 | 106.1 | **255.2** | **280.9** | **306.5** |
| Explosives | | | | | | | 24.5 | 24.5 | 24.5 | **24.5** | **24.5** | **24.5** |
| Technical textiles | 90 | 194 | 298 | | | | 319 | 385 | 452 | **409** | **579** | **750** |
| Broader industrial uses | 2.1 | 11.4 | 20.8 | 27.5 | 150.9 | 274.3 | | | | **29.5** | **162.3** | **295.1** |
| **TOTAL with stock**[h] | **2 787** | **7 359** | **11 927** | **46 857** | **49 812** | **52 767** | **8 112** | **15 950** | **23 792** | **57 780** | **73 179** | **88 578** |
| Total (new to market)[i] | 2 787 | 7 359 | 11 927 | 17 913 | 20 868 | 23 823 | 8 148 | 16 009 | 23 873 | 28 836 | 44 234 | 59 634 |

a) In some cases, a basis for providing a range is lacking. There the available estimate is applied throughout. Emissions from PFAS manufacture are not included in the emission estimates for the different use sectors. The table only presents those values which are clearly attributable to specific PFAS groups. If emissions could not be clearly attributed to one PFAS group, the corresponding emissions are presented together with those that could be attributed under 'Total PFASs'. This can lead to the 'Total PFASs' column showing higher values than the sum of its different PFAS groups. Note that the values presented in this table differ from those presented in Annex B, as this table does not include end-of-life emissions. Active substances (PPP, BP, MP) are not considered here because these substances are are already taken into account in their respective regulations, and concerns are addressed there.

b) The emissions for "Manufacture" refer to the total emissions of PFAS as substances on their own manufactured in the EEA.

c) TULAC = Textile, upholstery, leather, apparel and carpets;

d) No data available for emission of polymeric PFASs;

e) The emission estimates for cosmetics include 0.12 tonnes of TFA, which is a PFAA, remaining as residual from the manufacture of non-PFAS peptides for cosmetic use as well as 0.015-64.2 tonnes of various PFAS intentionally used in cosmetic products. Due to limited information, no tonnages per sub-category of PFAS are specified for PFAS intentionally used in cosmetic products. Table A.116 in Annex A ranks the most frequently found PFASs in cosmetic products;

f) For these sectors the emissions were derived from tonnage estimates of the technical stock (presented in italics) and not from tonnage estimates of annual manufacture. For reference only, the emissions from tonnage brought new to market in 2020 are also given;

g) Emissions reported for the sake of completeness, but not included in the total to avoid double counting as the uses are already covered in other sectors;

h) Total based on emissions from best available data (stock if available, new to market if stock is not available);

i) For reference only, also the total emissions from tonnage brought new to market in 2020 is presented.

PFASs in applications of fluorinated gases, transport, and PFASs in TULAC applications are applications with the largest PFAS load to the environment (excluding the waste stage), see Table 1. For TULAC this is partly linked to the high PFAS tonnages used in the products. High emission percentages compared to tonnage used are seen in other medical applications and applications of fluorinated gases as well as in consumer mixtures, cosmetics, ski wax and petroleum and mining (see Table 4 in section 1.3.1).

The emission estimates presented in Table 1 represent estimates obtained in the base year 2020s. Technological and market developments can cause specific markets to shrink or grow, depending on economic developments such as, for example, the demand of products (see also section 1.3.2 for information on market developments). For all sectors except for the fluorinated gases and the transportation sector, 2020 emissions estimates were derived from data about the annual manufactured tonnage. In contrast, emission estimates of the fluorinated gases and (of fluorinated gases in) the transportation sector comprise emissions from 'manufactured products' (depending on the quantities brought new to the market), and from emissions in the use phase due to re-filling (depending on the technical stock). For further details regarding the method for assessing environmental impacts cf. section 2.4.3.1. Next to existing uses of PFASs, new uses are likely to emerge in the future. These could add to future emissions. It is recognized though that it is impossible to provide a fully exhaustive inventory of uses, tonnage and emission estimates given the large number of PFASs and the broad range of processes and products they are used in. Given the extent of stakeholder engagement, it is envisaged that all of the major applications of PFASs have been identified. There is a good understanding of the desired functions and properties provided by PFASs for each application (see e.g. Annex A, Table A.1.)

#### 1.1.5.5. Emissions from waste management

PFASs enter the waste stage for many of the investigated applications. The fraction of PFASs entering the waste stage may differ between uses. For some applications nearly all emissions occur during use phase, e.g. application of fluorinated gases as propellant, for other uses the largest part will enter the waste stage, e.g. fluoropolymers in electronics. The end of life stage/waste management can be an important secondary (point) source of PFAS emissions and can be considered a cyclical problem, as current waste management approaches return either the original PFASs or their degradation products to the environment (Stoiber et al., 2020).

Waste collection and transport is one of the first steps before waste treatment. Uncontrolled spreading and diffuse emissions of (surfactant-like) PFASs in waste transport have been documented. In the Netherlands, solid and liquid waste containing HFPO-DA was emitted to the environment as a result of waste management supply chain activities (transport) in 2018/2019 (ILT, 2018; ILT, 2019). After collection, waste is often bulked and pre-sorted at waste transfer stations. There are at least 2 400 waste transfer stations in the EEA (FEAD, 2021). As research has shown, emissions, especially to water, are very likely at waste transfer/recycling stations (RWS, 2020).

Recycling of PFASs, especially fluoropolymers, is difficult – particularly for post-consumer waste – as PFASs, and mainly fluoropolymers, are typically compounded with other materials and fillers (and vice versa). Downstream users of fluoropolymers may be applying various recycling loops and manufacturers of PFAS look into ways to recycle used fluoropolymers from concentrated waste streams, although it currently is mainly concentrated on scrap from production and manufacturing (Wahlström et al., 2021). Downstream users may apply different types of recycling options in their own production sites. Several stakeholders provided information on fluoropolymer recycling (e.g., #6056, 8521, 5935). If recycling takes places, this is generally primary or secondary recycling (mechanical). The only chemical recycling in the EEA takes place at Dyneon in Bürgkirchen, Germany, at a facility where also primary production of PFAS takes place. Other initiatives are on pilot scale (Ameduri and Hori, 2023; Schmidt-Rodenkirchen et al., 2022 in: chapter 9.6, Niessner, 2022).

The presence of PFASs in materials that are generally intended to be recycled after use, can be a relevant emission source of PFASs to the environment, e.g. foam blowing agents used for insulating for district heating pipes is released again when pipes are shredded for recycling purposes, including the PFAS-containing insulation material. Also, emissions and worker exposure in/around sites where electronic waste are handled for recycling have been reported (e.g. Garg et al. (2020), Peng et al. (2022)). Except for fluorinated gases under the F-gas regulation, there is no legal obligation and/or incentive to recycle (or fully destruct) PFAS-containing waste.

Measures mentioned by stakeholders to reduce emissions at the end of life of articles are e.g. collection of industrial waste, recycling or the implementation of traceability systems for parts containing PFASs and take-back systems (e.g. comment IDs #4257, 4307, 4447, 6268, 6293, 6500, 6514, 6598, 6791, 6808, 8182, 8369, 8375, 8695, 8900). Current recycling of fluoropolymers seems to be in the range of 3% of all FP-waste according to stakeholder information (responses to the consultation on the Annex XV report e.g. comment IDs #5929). Other RMMs mentioned by stakeholders are provisions for waste management e.g. high temperature incineration or similarly effective treatment requirements according to provisions set out in European regulations such as Directive 2008/98/EC on waste framework, Directive 2012/19/EU on waste electrical and electronic equipment, Directive 2000/53/EC on end-of life vehicles, or Directive 2010/75/EU on industrial and livestock rearing emissions (e.g. comment IDs #3891, 3996, 4014, 4196, 4212, 4240, 4307, 4417, 4432, 6268, 6293, 6471, 6514, 6791, 6806, 6928, 7099, 7569, 8182, 8269, 8306, 8363, 8369, 8375, 8695, 8714, 8734, 9011, 9383, 9388). Most commonly stakeholders state that incineration at/above 800 °C for more than three seconds is guaranteed (e.g. comment ID #4417). Landfilling is also mentioned by several stakeholders as a safe disposal method. Due to the properties of the fluoropolymers, decompositions, emissions and leaching are not possible (e.g. comment IDs #4307, 6520). For some sectors, however, recycling is not possible due to chemical contamination as indicated by a stakeholder (comment IDs #4014).

In the Dossier Submitters' view, landfilling, wastewater treatment and incineration broadly are currently insufficient to enable complete avoidance of PFAS emissions (see Annex B.4.5., B.7.6. and B.9.26)

Landfilling, wastewater treatment and incineration are the most relevant waste treatment methods. In landfills, PFASs are not destroyed and eventually may enter the environment via leachate/air or are sequestered in the landfill (possibly leading to delayed emissions when environmental conditions change). In waste incineration, PFAS are destroyed but 100% complete destruction is not to be expected at operational conditions, especially for municipal waste incineration, since PFAS removal and destruction efficiencies depend on the structure of PFASs, but also on the operational conditions like the presence or absence of oxygen, the presence or absence of other chemical substances, temperature, etc. (Longendyke et al., 2022). In general, PFAS emissions from waste incineration are not well studied, but it is clear that the efficiency of the destruction method depends on numerous (operational) conditions (e.g. mentioned in Appendix 2 in ECHA (2022)). Discharge of PFAS-containing wastewater to wastewater treatment plants (WWTPs) asks for advanced removal techniques to eliminate PFASs before discharge to surface water. In general, (municipal) WWTPs are not equipped to remove PFASs from influent, leading to discharge of PFASs to surface waters (STOWA, 2021). In several cases, PFAA concentrations in effluents were even higher than in influents, with biodegradation given as the primary mechanism responsible for the transformation of (measurable) PFAS precursors to PFAAs (Lenka et al., 2021).

Waste management and treatment facilities are relevant point sources for PFAS waste stage emissions. It is estimated by PlasticsEurope that in the EEA approximately 15% of fluoropolymer waste is landfilled and 80% is incinerated going through (municipal waste) incineration with energy recovery (Conversio, 2022). According to European waste statistics for 2018, 38% of the waste is landfilled. Significant differences can be found between different EU Member States, ranging from approximately 5% to 100% landfilling[9].

Emission factors for landfilling, WWTP and incineration, based on PFAS input/output tonnage, could not be derived by the Dossier Submitters (see Annex B.9.26.). In many studies PFAS output from different types of waste treatments has been partly determined with (mostly dedicated) PFAS sampling and analyses. However total PFAS input for these types of waste treatment options are unclear and therefore a reliable release factor cannot be derived. Calculations were conducted individually for the assessed uses using the approach outlined in Annex B.9.26.2.10.

New PFAS destruction technologies are being investigated, but often on a laboratory scale and these new technologies all have their specific advantages and disadvantages (Meegoda et al., 2022; Trang et al., 2022; Verma et al., 2023). These technologies have in common that they cannot be efficiently or in an economically feasible manner applied to PFASs that already entered the environment. One stakeholder also states that the Digital Product Passport will allow better traceability of the pumps and the components in question (comment ID #6514). Stakeholders also inform on an upcycling concept splitting polymers back to their monomers at temperatures above 600 °C for reuse (e.g. comment ID #4417, 6520), which could prove to be a suitable approach in view of circularity.

### 1.1.5.6. Conclusion on emissions

PFASs are used in many sectors, and even within the same sector there are many sub-applications. Around 265 000 t of PFASs/y (excluding manufacture) are used in substances, mixtures and articles in the EEA (midpoint, see Table 3 in section 1.3.1). Emissions to the environment as a result of the use phase (but excluding the waste phase) are estimated to be around 73 000 t of PFASs/y (midpoint) in the EEA (see Table 1). While RMMs and OCs in the manufacturing of PFASs and in the further processing of these to mixtures and articles limit emissions to the environment, there are many examples of PFAS hotspots in close proximity to PFAS manufacturers and PFAS formulators (see Annex B.7.6. and Table B.78 in Appendix B.4.2.1.3.). These show that current RMMs and OCs are not adequate to reduce the emissions to an acceptable level.

Emissions also occur during the use phase (service-life) and waste stage. In the use phase, articles seldom contain instructions for RMMs and OCs in view of emission reduction. In the waste phase, unless used by professionals in industrial uses, PFAS articles are also managed via normal waste streams. The current waste management measures however are not fully equipped to ensure a complete destruction of all PFASs (see Annex B.9.26.). A major part of PFAS emissions come from applications of fluorinated gases, medical uses, TULAC and transport, which are responsible for the emission of approximately 53 000 t of PFASs/y (excluding waste stage emissions).

Regarding PFAS tonnage, TULAC, applications of fluorinated gases, transport, sealing applications and electronics and semiconductors are the most relevant sectors according to the research. Emissions from niche applications that have not been considered, from expected growth markets (e.g. oil fracking), and emissions from the waste phase are not considered in the 73 000 t PFAS emissions per year, so actual emissions likely are higher than this estimate. It is recognized though that it is impossible to be complete, given the large number of PFASs and the broad range of processes and products they are useful for. From literature and stakeholder consultations indeed some additional uses/applications were identified. For these, however, no detailed assessment was performed, e.g. because they concerned niche

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[9] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics#Waste_treatment, date of access: 2022-12-21.

applications or because the applications are currently of little relevance in the EU. However, the Dossier Submitters consider all uses with relevant emissions covered in this dossier.

PFAS emissions resulting from article production are largely unclear, as important information is missing. With an estimated number of EEA point sources over 100 000, this could be a relevant PFAS emission source. For many products there is a long use phase in between production and waste stage. Significant amounts of PFASs are therefore in "technical stock", i.e., in long-lived products like coated articles, construction materials, electronics, solar panels, applied paints and lubricants, etc. Fluoropolymers are the main group of PFASs to enter the waste stage and waste stage emissions are highly uncertain.

The effectiveness of incineration to destroy PFAS and the tendency for formation of fluorinated or mixed halogenated organic by-products is not well understood (Lohmann et al., 2020).

Especially in landfilling, sequestration or 'building up' of PFASs may occur. Leaching is concentration dependent, with more rapid leaching found at higher concentrations of PFAAs (Kah et al., 2021; McLachlan et al., 2019). PFAS emissions to air and water (leachate) will continue for decades to come, even if landfills are closed (Propp et al., 2021). As a result "environmental stocks" will build up resulting from the waste stage of PFAS-containing substances and products, mainly in landfills and WWTP sludge that is not incinerated. Another example is sequestration in landfill: up to 85-99% of PFAS is (temporarily) sequestered (SANBORN, 2019).

Even with a restriction in place, due to prolonged article use, recycling of old materials, and slow release of PFASs from landfills, PFAS emissions are expected to continue far after a restriction is in place.

### 1.1.5.7. Environmental monitoring data

PFASs are ubiquitously found in European environments and biota. Numerous examples of highly contaminated environmental matrices, such as soil and drinking water, near different types of point-sources have been reported and many more cases are likely to go undetected. This section provides a short summary of environmental monitoring data findings, for more information and detail see Annexes B.4.2.6. and B.4.2.7.

Monitoring studies of targeted PFASs in environmental matrices show that PFOS and PFOA, which are restricted, still are the dominating PFASs in soil, sediment, sludge, and biota, and among the most abundant PFAAs in aquatic environments. Thus, despite the phase-out of PFOS and PFOA, they are still detected at high levels worldwide, illustrating that contamination of PFASs is poorly reversible and underpins the need to restrict also other PFASs to avoid similar problems in the future. Furthermore, the presence of precursors, such as side-chain fluorinated polymers, will remain a long-lasting source of PFAAs in the environment even after a phase-out of production.

The ban of PFOS and PFOA has resulted in a transition to other PFASs, such as shorter chain PFAAs and PFAEs. For example, HFPO-DA is widely detected in the European environment, whereas 6:2 Cl-PFESA is found in high levels in China, but currently not in Europe (Heydebreck et al., 2015; Joerss et al., 2019; Pan et al., 2018). Besides these most studied PFAEs, studies have clearly shown the presence of other, sometimes even more abundant PFAEs in the vicinity of fluorochemical industries (Song et al., 2018; Strynar et al., 2015; Sun et al., 2016). However, little is known about the general environmental levels of these and other PFAEs. Furthermore, very little is known about the levels of polymeric PFASs in the environment, partly due to analytical limitations. However, both side-chain fluorinated polymers and fluoropolymer microparticles have been detected in the environment.

Shorter chain PFAAs often account for a major part of the total known PFAA content in water samples, including drinking water. In particular, the ultra-short (C1-C3) PFAAs (including TFA), have been found at high levels and constitute a large part of the total PFAS content in aquatic matrices such as drinking water, WWTP effluents, waters close to point-sources, and precipitation (Aro et al., 2021; Björnsdotter et al., 2019; Chen et al., 2019; Freeling et al., 2020; Neuwald et al., 2022; Wang et al., 2020). In the light of the high persistence of these non-restricted compounds, their high mobility, low adsorption to organic carbon and the difficulty to remove them from water, the concentrations of these compounds will increase if emissions of these compounds and/or their precursors to the environment continue.

Studies on EOF/AOF in environmental samples and mass balance analysis show that varying but significant fractions of organofluorine are unknown and therefore not captured by monitoring using only targeted PFAS analysis (Table B.82. and Table B.83. in the appendix of Annex B). There are indications that higher trophic levels display a lower fraction of unknown organofluorine, possibly due to metabolism of precursors into the stable PFAAs which are often included in the targeted analyses. Studies of abiotic and biotic samples utilizing TOPA demonstrate that considerable fractions of PFASs in the samples may be comprised of unknown oxidizable PFASs that are not detected in routine target analyses, including precursors to the rarely analyzed C2-C3 PFCAs (Gockener et al., 2022; Joerss et al., 2020; Simonnet-Laprade et al., 2019). Thus, environmental samples commonly contain PFASs with unknown identity and regulatory status and the total PFAS mass balances may be underestimated without treatment with TOPA. Similarly, non-target and suspect screening methods, applied to identify compounds constituting the unknown organofluorine fraction, have (tentatively) identified hundreds of different PFASs in various environmental samples (Liu et al., 2019). These substances would go undetected if only targeted analyses with available reference standards were performed. However, the suspect and non-target screening can only provide qualitative and semi-quantitative data of substances, and not quantitative, giving limited value to mass balance calculations. Although this information clearly demonstrates that targeted analyses of individual PFASs do not provide the full picture of PFAS contamination, the vast majority of studies have applied such methods. While most of these studies have analysed a limited number of compounds, limited data are available on the occurrence and/or concentration of other PFASs, such as PFAEs and C1-C3 PFAAs.

Whereas time trends of PFOA and PFOS are decreasing in humans, the trends in biota are inconsistent (Land et al., 2018). Regarding time trends in aquatic environments, the levels of PFOS and PFOA seem to be decreasing in European and North American coastal, sea and river waters (Land et al., 2018; Muir and Miaz, 2021). However, it has to be noted that phased-out PFASs that may show declining trends locally are not disappearing on a global scale due to their potential for long-range transport and persistence in various compartments. For most PFASs, including PFAEs and shorter chain PFAAs, there is limited or no temporal trend data. The clearest increasing time trend is observed for the fluorinated gases that have replaced CFC after the implementation of the Montreal Protocol (AGAGE, 2022; NILU, 2021). A simultaneous increase of TFA in air, precipitation and plants is likely a result of the increase of TFA-yielding gases (Freeling et al., 2020; Freeling et al., 2022; Zhai et al., 2015). In addition, analyses of ice/firn cores show increasing atmospheric deposition of TFA, PFPrA and PFBA over time (Kirchgeorg et al., 2013; Pickard et al., 2020).

### 1.1.5.8. Human exposure assessment

The ubiquitous presence of PFASs in environmental media and widespread use in many types of consumer products lead to an array of potential exposure sources (see Annexes B.9.29. and B.9.30.). For the general population (i.e. individuals who are not occupationally exposed or living in contaminated hot spots), exposure routes include ingestion of food and water, intake of indoor dust, inhalation of air and contact with consumer products (De Silva et al., 2021; Haug et al., 2011; Poothong et al., 2020; Vestergren et al., 2012; Vestergren and Cousins, 2009). The dominating exposure route varies greatly for different PFAAs, reflecting their physico-chemical properties and use patterns. For hydrophobic and bioaccumulative long-chain PFAAs, dietary intake (especially of fish and meat) is typically the most important exposure route, whereas for highly water soluble short-chain PFAAs, drinking water and other food categories, such as vegetables, tend to be the dominating exposure routes (EFSA, 2020; Vestergren et al., 2012). For precursor compounds, exposure to consumer products (e.g. impregnation products) via the indoor environment is probably the major exposure route (Vestergren et al., 2008). For occupationally exposed individuals, who often may have a higher exposure, the primary routes to PFAA exposure are inhalation, ingestion of dust and dermal uptake at the workplace (De Silva et al., 2021; Fu et al., 2015). Regarding other non-polymeric PFASs, such as PFAEs, the relative contribution from different exposure routes in the general population has not been described.

The bioavailability and thus the potential for human exposure to fluoropolymers has been an issue for discussion. In summary, it has been proposed that absorption of fluoropolymers in humans is obstructed due to their large sizes (Henry et al., 2018). On the contrary, it has been argued that the production, processing, use, and end of life treatment of fluoropolymers lead to emissions of bioavailable compounds (e.g. monomers, oligomers, decomposition and combustion products, PFAA/PFEA polymerisation aids, additives, unintentional PFAS by-products, impurities, and particles), which may be relevant for human exposure (Lohmann et al., 2020). Toxicokinetics of oligomeric/polymeric PFASs are further described in Annex B.5.1.2. Regarding side-chain fluorinated polymers, potential degradation to more bioavailable PFASs may add to the exposure to these compounds in humans.

Human biomonitoring studies of known PFASs unambiguously demonstrate world-wide exposure to a wide range of PFASs, with especially high exposure levels in populations living in areas close to PFAS point sources as well as in occupationally exposed individuals. In the general European population, PFOS, PFOA, PFHxS and PFNA are the most studied and most abundant PFAAs. Furthermore, exposure of a considerable part of the European population exceeds the tolerable weekly intake derived by EFSA (2020) for these PFASs. The high levels of PFASs that have been phased out demonstrate that the historic exposure takes a long time to reverse. In addition, it is evident that the European population is also exposed to PFAAs that are not covered by current or proposed restrictions.

In the US and China, several PFAEs have been detected in blood from populations living close to fluorochemical manufacturing facilities. In addition, 6:2 Cl-PFESA is generally the third most abundant PFAS in blood of the Chinese population. These studies indicate that a potential increased use of PFAEs as substitutes for legacy PFASs could lead to increased human exposure also in Europe. However, blood levels of the most studied PFAEs (ADONA, HFPO-DA, 6:2 Cl-PFESA) are currently low in the general European population.

In addition to known PFASs analysed by targeted analysis, humans are exposed to a considerable amount of organofluorine compounds for which the identity and consequently the regulatory status and health effects are unknown. Fluorine mass balance analyses of human blood show substantial variation (0-97%) in the proportion of unknown organofluorine to the total concentration of organofluorine reported in different studies, demonstrating that human exposure is likely underestimated when only taking known PFASs into consideration, and emphasise the need for a universal PFASs restriction to protect human health.

## 1.1.6. **Risk characterisation**

The PFASs in the scope of this restriction proposal exceed the vP criteria of Annex XIII of REACH, either themselves or when degrading to arrowhead PFASs. The half-lives of the most stable PFASs (e.g. PFAAs) are known to be in the order of decades to centuries, thus exceeding by far the vP criteria, which vary from 40 to 180 days depending on the matrix. Due to the high diversity of the PFASs the bioaccumulation potential and ecotoxicity/toxicity are expected to vary among the substances. Therefore, no overall conclusion on B/vB and T criteria was derived for each PFAS substance/(sub-)group (see also sections 1.1.4.6 and 1.1.4.7). The very high persistence is not sufficient to identify the PFASs as PBT or vPvB substances. However, the additional properties described above combined with the very high persistence add substantially to the overall concern which is very similar to those of the PBT/vPvB substances. Therefore, the case-by-case approach is investigated below.

### 1.1.6.1. Case-by-case assessment according to para 0.10 of Annex I to REACH

The procedures in sections 1 to 6 in REACH Annex I are impracticable to describe the particular effect of PFASs in the scope of this restriction proposal, as these PFASs are very persistent (vP) in combination with identified and possible other concerns. Therefore, the risk is described on a case-by-case basis.

As summarised in section 1.1.4 on the properties of concern, PFASs have a high potential for ubiquitous and increasing exposure of the environment. This can lead to irreversible damage to the environment and humans. With current use patterns, and considering the expected market growth of several sectors using PFASs, the environmental pollution burden (i.e. the environmental pollution stock, which is the mass or concentration of PFASs at the local, regional, continental and global scale) can be expected to continue to increase over time. PFASs or their degradation products have half-lives of many years. Thus, a constant emission path will result in a growing stock in the environment. The stock path over time depends on (i) PFAS emissions during the production, use, and end of life (waste) phase, (ii) persistence, physico-chemical and fate properties (e.g. water solubility, volatility, mobility), and (iii) environmental conditions.

Considering the growing environmental PFAS stock in combination with a difficulty for decontaminating soil or intake water used for drinking water production at large scales, as well as the low effectiveness of end-of-pipe wastewater treatment, this triggers a high potential for very long-term human exposure via food and drinking water. These properties together, in addition with long-term transfer mechanisms, lead to a high potential for intergenerational effects.

Due to the complex co-occurrence of PFASs in the environment and the very long-term exposures, standard tests do not provide sufficient understanding of possible effects. Furthermore, quantification of future exposure levels and safe concentration levels is highly uncertain for PFASs, due to the exposure to mixtures of PFASs in the environment, complex degradation patterns of precursor PFASs to arrowheads, and due to the very high persistence and hence exposure times reaching decades if not centuries. Combined effects may be expected for PFASs. The significant global warming potential of many volatile PFASs adds yet another concern to the picture.

Because of the very high persistence of PFASs, their mobility and long-range transport potential, concerns have been expressed about whether their releases into the environment might ultimately reach or have arguably already reached concentration levels that could breach so-called ‘planetary boundaries’ – a point at which the earth is no longer able to assimilate or degrade a human-released chemical. In consequence, the release, if discovered too late, can have a disruptive and irreversible effect on ecosystem functioning and on a vital earth system as a whole (Cousins et al., 2022). Any effects of such a pollutant cannot be readily reversed (Diamond et al., 2015; Persson et al., 2013). At the time when notable effects from PFASs exposure occur in the environment it will be difficult, if not impossible, to remove the contamination. Due to the ubiquitous occurrence of PFASs this may ultimately lead to an impairment or total loss of important natural resources, as well as increased overall pressure on human health and the ecosystems (Goldenman, 2017). Examples could be a loss in biodiversity or impaired ecosystem services (in particular provisioning services and regulating services).

Continued emissions of PFASs (including from the end of life phase of products) will result in an increasing environmental stock and, hence, increasing exposures. This results in a high likelihood that known thresholds of PFAS to cause adverse effects are exceded - as well as of yet unknown thresholds - and that, as a consequence, toxic effects will manifest at some point in the future. Additionally, the persistence of PFAS must be considered to act as a multiplier of their toxicity (Scheringer, 2023).These would be caused by single PFASs and/or in a mixture with other PFASs. It should be noted that for the most sensitive endpoints related to human health, such as effects on the immune system, and in highly exposed populations, effect thresholds of the most studied long-chain PFASs (PFOA and PFOS) are already exceeded today (EFSA, 2020).

Overall, PFASs should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances. Their releases can be accordingly used as a proxy for risk. To minimise the likelihood of adverse effects in the future, all releases should be minimised.

Section 1.1.5 summarises the information on the current releases of PFASs to the environment. Manufacture, placing on the market and use of some PFASs have already been restricted in the EU (e.g. PFOA, PFOS and, as of February 2023, C9-C14 PFCAs and their salts and related substances) or are in the process of being restricted (e.g. PFHxS and PFHxA and their salts and related substances, PFASs in firefighting foams), however most of the PFASs still need to be addressed by regulatory risk management. Monitoring data for some PFASs show that PFASs are ubiquitously distributed in the environment (see Annex B.4.2.). It should be noted that so far only a limited subset of PFASs are addressed in monitoring programs and therefore current monitoring results are expected to provide only an incomplete picture of the overall exposures to PFASs (see Annexes B.4.2.6. and B.4.2.7.).

In conclusion, the ongoing releases of PFASs are causing the environmental pollution stock and subsequent exposures to increase over time. Combined with the non-threshold nature of the hazard, this warrants an urgent need for minimisation of the releases. The proposed restriction aims to effectively stop or considerably reduce environmental PFAS pollution, which could otherwise lead to very long-lasting and potentially irreversible damage.

It is noted that RAC supported the proposal to restrict intentionally added microplastics and PFHxA based on a closely similar case-by-case hazard and risk assessment approach (ECHA, 2020; ECHA, 2021a). Analogously, a specific case for excluding a PFAS from the scope of the proposed restriction could be made if sufficient evidence is provided that the specific PFAS is not very persistent itself and does not degrade into a very persistent PFAS. This is also addressed in section 1.1.1.

#### 1.1.6.2. Emissions as a proxy for risk

Without restriction of the manufacture, placing on the market and use of PFASs, emissions of these substances will continue. As a result, due to the persistence of PFASs, the environmental stock will continue to grow both in the EU and globally. This leads to a growing risk of negative environmental and health impacts and, thus, damages over time. A restriction will reduce emissions. This will lead to a reduction of the pollution stock in the environment, though it comes with a delay depending on the persistence of PFASs. For PFASs which do not degrade at all, or where degradation is very limited, a restriction can at least prevent the stock from increasing further.

In case of very persistent substances, the relevant unit for a concern-based evaluation of restriction measures' risk reduction potential is the environmental stock (Conrad and Olson, 1992; Gabbert et al., 2022; Hart and Brady, 2002; Mackay et al., 2014). Stock assessments have been used earlier for evaluating the effectiveness of restriction measures for persistent chemicals in general, and for PFASs in particular, for example in the REACH Annex XV dossier on PFHxS (ECHA, 2019b). Assessing the stock requires information about physico-chemical and fate properties of PFASs, and about their persistence under environmental conditions. For a large number of chemicals covered by the restriction proposal this information is still incomplete. Furthermore, existing information is often uncertain. Therefore, emissions will be used as a proxy for risk. To evaluate the effectiveness of restriction options, and the corresponding expected emission reduction, emissions will be used as a proxy for the risk reduction capacity of the specific restriction options. While emission estimates inform about the pollution flow into the environment, they do not reflect the accumulation of pollution over time due to persistence. It is therefore important to note that a use of emission estimates as a proxy for risk will likely underestimate impacts to be expected, and in particular long-term impacts and damage costs.

## 1.2. Justification for an EU-wide restriction measure

Section 1.1 illustrates the hazards and combined concerns associated with PFASs. In section 1.1.5 an overview of the current releases and exposures due to the ubiquitous use of PFASs is provided. Section 1.1.6 summarises that due to the non-threshold nature of the hazards, the risks cannot be quantified and that current releases of PFASs should be minimised. Any release should be considered a proxy for risk. Due to the ongoing releases, the risks are currently not adequately controlled. Based on this unacceptable risk for human health and/or the environment identified for the group of PFASs, measures are needed to minimize the releases to the environment and reduce human exposure to a minimum.

PFASs are manufactured globally. The global PFAS tonnage manufactured is not entirely clear. It is estimated that in between ca. 120 000 and 400 000 t/y of PFASs are manufactured in the EEA (see Annex A.2.). Due to their properties, perfluorinated substances are used for manufacturing of articles and mixtures in large quantities and for a large variety of applications in the EU/EEA. While in some sectors and uses PFASs have been increasingly replaced by fluorine-free alternatives, in some cases substitution is not happening even though PFAS-free alternatives are available (see Annex E.2.). Additionally, numerous sources indicate that globally fluoropolymer production will increase significantly in the next years. A large variety of emission sources contribute to the exposure of humans and the environment to PFASs (see Annex B.9.) with surface water and soil being the key receiving environmental compartments. Some PFASs were shown to be ubiquitous contaminants, for instance in arctic wildlife (Muir et al., 2019).

Based on the information presented in section 1.1.4.2, many PFASs are likely to persist in the environment longer than any other man-made organic substance. As a consequence, if releases are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are likely. In such an event the exposures are practically irreversible. Even if further releases of PFASs were immediately prevented, existing environmental stocks as well as technical stock (stock of PFASs in existing articles) and PFAS-containing waste would continue to be a source of exposure for generations. For technical stock, the size and longevity are determined by the length of the lifespan of the various articles, some of which (e.g. in construction products) can be used for decades. In combination this leads to irreversible adverse effects on the environment and on human health over time (see Annexes B.4., B.5. and B.7.). Removal of contamination is technically challenging, energy intensive, and thus costly. Additionally, costs of health care, loss of biodiversity, loss of ecosystem services and loss of property value (Cousins et al., 2020b) need to be taken into account. Therefore, a preventive approach of not using highly persistent synthetic organic substances is more protective and also overall less costly for society.

Monitoring studies demonstrate the ubiquitous presence of perfluorinated substances of both, known (e.g. PFOA, PFOS, PFHxS and other long chain perfluorinated substances (C9-C14 PFCAs and PFSAs)) and varying fractions of unknown organofluorine substances in all environmental media including ground water and drinking water (see Annexes B.4.2.6. and B.4.2.7.). Widespread occurrence of the very persistent substances in the environment, e.g. via aqueous compartments or via the atmosphere, potentially lead to global distribution (see Annex B.4.2.8.). Additionally, soil can serve as long-term reservoir for PFASs and potentially be a long-term source of contamination for groundwater (see Annex B.4.2.3.). Thus, effects will not only occur at the point of release but also at some distance from that point. Therefore, it may affect a very large number of people. Human biomonitoring demonstrates that the EU/EEA population is exposed to various PFASs (see Annex B.9.30.). Furthermore, exposure via food and drinking water leads to elevated concentrations of various PFASs in human blood (see Annexes B.9.29.1. and B.9.29.2.). Consumer articles are a source of PFASs for human exposure both directly at use and indirectly via the indoor environment (e.g. house dust and air, see Annexes B.9.6. and B.9.29.4.). Relevant articles such as food contact materials or textiles are placed on the market and used in all EU/EEA Member States. A considerable share of articles containing PFASs is imported from outside the EU/EEA (see Annex A.2.2.). Exposure of perfluorinated substances to humans, wildlife and the environment occurs in all EU/EEA Member States. A Union-wide restriction is needed as the mobility and persistence of PFASs lead to cross-border pollution that cannot be adequately managed by several national regulatory actions.

An EU/EEA wide restriction will prevent and reduce the manufacture, placing on the market (including imports), use and release of PFASs within the EU/EEA in a harmonised manner. PFASs and articles containing PFASs produced in one Member State may be transported to and used in other Member States. Even if measures were introduced at Member State level, there is potential for discrepancies in the definitions and scope of any national restrictions (e.g. definition of substances covered, uses covered, concentration thresholds, and transition periods). This has implications not only for the degree to which the environment and human health is protected, but also in terms of ensuring the functioning of the internal market. Union-wide action avoids trade and competition distortions within the EU/EEA, thereby ensuring a level playing field in the internal EU/EEA market as compared to action undertaken by individual Member States. Additionally, the emitted substances are transported across global borders via air and water. Hence, EU-wide measures for risk reduction are the only way to implement controls efficiently and uniformly within the EU/EEA. An EU/EEA restriction also allows an adequate regulation of imported articles containing these substances. Moreover, a restriction within the EU/EEA may be the first step for global action, which is needed as PFASs and PFAS-containing products are manufactured and distributed in a global market.

# 1.3. Baseline

## 1.3.1. **Manufacture and use – Introduction and current situation**

Due to their typical properties like chemical inertness, radiation resistance, temperature resistance, weathering resistance, oil-, water- and stain repellence, electrical inertness, corrosion protection, low coefficient of friction and non-flammability, PFASs are used in many industry sectors, in a very broad range of applications. From the scientific literature, information obtained during two stakeholder consultations (call for evidence and 2nd stakeholder consultation) and additional stakeholder input (e.g. from targeted stakeholder interviews) various uses and sub-uses of PFASs were identified. Data on the PFAS group(s) used, the tonnages corresponding with the use of PFASs and the emissions emerging from that use were assessed in detail for all uses/use sectors where sufficient information was available for the initial submission of the dossier in 2023. From literature and stakeholder consultations some additional uses/applications were identified. For these however no detailed assessment was performed, e.g. because they concerned niche applications or because the applications are currently of little relevance in the EU. For some uses, the Dossier Submitters decided to await further input from the Annex XV report consultation in 2023 to fully assess them. Based on this input, the following additional uses were also assessed:

- Printing applications
- Sealing applications
- Machinery applications
- Other medical applications
- Military applications
- Explosives in civil applications
- Broader industrial uses

Furthermore, for some of the already established uses new information from the consultation on the Annex XV report led to the addition of further sub-uses. It is recognized though that it is impossible to provide a fully exhaustive inventory of uses, tonnage and emission estimates given the large number of PFASs and the broad range of processes and products they are used in. Given the extent of stakeholder engagement, it is envisaged that all of the major applications of PFASs have been identified. There is a good understanding of the desired functions and properties provided by PFASs for each application.

Table 2 presents an overview of these uses/use sectors (and sub-uses within). Table 3 presents the estimated tonnages for these sectors for 2020, supplemented with the 2020 estimated tonnages for PFAS manufacture (see Annex A for detailed information on manufacture and use). These tonnages were used as basis for estimation of the PFAS manufacture, PFAS use and service life emissions in 2020 (see section 1.1.5.1 for details and Table 1 therein). The estimated tonnages and emissions form the basis for the impact assessment. For impact assessment purposes, tonnages are not only presented for total PFASs per sector but, where possible, also for three main PFAS groups therein, i.e.:

1. PFAAs and PFAA precursors
2. Fluorinated gases
3. Polymeric PFASs

While side-chain fluorinated polymers chemically belong to polymeric PFASs, i.e. Group 3, their tonnages are allocated to PFAAs and PFAA precursors, i.e. Group 1, for impact assessment purposes.

It is also important to note that information density varied substantially across sectors and uses and therefore not every single application has been assessed in detail regarding the aspects described above. However, *all* applications are covered by the scope of the restriction proposal because PFASs used eventually end up in the environment due to releases resulting from PFAS manufacture, use, service life or due to waste handling operations.

**Table 2. PFAS main applications and sub-uses.**

| | | | | | | | | | | | | | |
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| **Firefighting foam** | Covered by separate restriction proposal | | | | | | | | | | | | |
| **TULAC (Textile, upholstery, leather, apparel and carpets)** | Home textiles | Consumer apparel | Professional apparel and PPE | Leather | Other: Home fabric treatments (sprays) | | | | | | | | |
| **Food contact materials and packaging** | Non-stick surfaces in consumer cookware and domestic appliances | Non-stick coatings in industrial and professional bakeware | Paper & board packaging | Use of polymer processing aids containing PFAS for production of plastic packaging | Packaging uses of F-HDPE (fluorinated high density polyethylene) | Other packaging applications | | | | | | | |
| **Metal plating and manufacture of metal products** | Hard chrome plating | Decorative chrome plating, chrome plating on plastics and plating with metals other than chrome | Manufacture of metal products not addressed elsewhere | | | | | | | | | | |

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| **Consumer mixtures and miscellaneous consumer articles** | Cleaners (for glass, metal, ceramic, carpet and upholstery) | Waxes and polishes (for e.g. furniture, floors and cars) | Dishwashing products (as rinse aids) | Windscreen treatments for automobiles and also windscreen wiper fluids | Anti-fogging agents for spectacles and goggles | Musical strings | Use in pianos | Fishing lines |  |  |  |  |  |
| **Cosmetics** | Cosmetic products | Peptide synthesis for cosmetic applications |  |  |  |  |  |  |  |  |  |  |  |
| **Ski wax** | Sector assessed as a whole |  |  |  |  |  |  |  |  |  |  |  |  |
| **Applications of fluorinated gases** | Refrigeration | Air conditioning and heat pumps | Foam blowing agents | Propellants | Cover gases | Clean fire suppressants | Preservation of cultural paper-based materials | Insulating gas in electrical equipment |  |  |  |  |  |
| **Medical devices** | Implantable medical devices (including medical implants and meshes) | Wound treatment products (non-implantable/non-invasive medical devices) | Tubes and catheters (invasive medical devices) | Other coating applications (non implantable medical devices) | Sterilization gases | Vision applications (invasive medical devices) | Packaging of medical devices |  |  |  |  |  |  |

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| | | | | | | | | | | | | | |
| **Transport** | Uses of fluoropolymers and perfluoropolyethers in transport vehicles [10](excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technica | Reflective coatings for traffic signs | Additives to hydraulic fluids in transport vehicles | Devices for motion control solutions | Mobile air conditioning and heat pump - systems | Transport refrigeration | | | | | | | |

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[10] This includes: Foam mouldings; Tubes and hoses in combustion engine systems; Protective coatings and paints for transport vehicles; Hydrophobic coatings for windshields; Cable liners & coatings for transport vehicles, including high-voltage insulators; Anti-fouling coatings for ships; Surface coatings for exterior sensors; Anti-icing coating for helicopter rotors; Trim materials for vehicle interiors; Coating of insulation materials; Coatings to reduce fuel consumption and emissions; FEP based heat shrink sleeving; Liners for aerospace hoses; and Wrap for aluminium fan cases for jet engines.

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| | l textiles) | | | | | | | | | | | | |
| **Electronics and semiconductors** | Wires and cables | Insulation material of electronic components | Coating / film of electronic components | Electronic components | Photonics | Plastic additives | Heat transfer fluids | Vapor phase soldering | Electronic data storage | Photolithography | Etching for semiconductor manufacturing | Deposition and engineered fluids | Semiconductor equipment |
| **Energy sector (sector assessed as a whole)** | Sector assessed as a whole | | | | | | | | | | | | |
| **Construction products** | Architectural coatings and paints | Coil coating | Film/foil for greenhouses | Window frames | Bridge and building bearings | Processing aids for production of non-PFAS polymers/plastics | Processing aids for production of construction articles | Polymer additives used for fire safety purposes | Surface protection | Wetting/levelling agents in e.g. coating, paints and adhesives | Window film manufacturing | Plumbing applications | |
| **Lubricants (sector assessed as a whole)** | Sector assessed as a whole | | | | | | | | | | | | |
| **Petroleum and mining** | Tracers | Anti-foaming agents | | | | | | | | | | | |

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| **Printing applications** | Toners | Latex printing inks | PTFE wax | Pigments and colourants | PTFE powders | Photosensitive materials | Electrophotographic press units | Kinetic printing components | Printing plates (offset and letterpress printing) | Rollers | Surfactant used in printing equipment | | |
| **Sealing applications (sector assessed as a whole** | Sector assessed as a whole | | | | | | | | | | | | |
| **Machinery applications (sector assessed as a whole** | Sector assessed as a whole | | | | | | | | | | | | |
| **Other medical applications** | Fluorinated gases as propellants in pressurized metered-dose inhalers (pMDIs) | Semifluorinated alkanes (SFAs) as excipients in medicinal products for ophthalmic and dermatological therapies | PFAS-coating in release liners and backing film in transdermal patches | Fluoropolymers in blisters for solid oral dose formulations | Fluoropolymer-coated rubber stoppers in vials/flasks for injectable medicinal products | Fluoropolymer-coated packaging of transdermal patches | Fluorinated HDPE packaging | Fluoropolymer-coated canisters in pressurized metered-dose inhalers | Fluoropolymer-coated plungers in pre-filled syringes | PFAS in pre-filled injection pens & autoinjectors | | | |

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| **Military applications** | Sector assessed as a whole | | | | | |
| **Explosives** | Sector assessed as a whole | | | | | |
| **Technical textiles** | Outdoor technical textiles | Architectural membranes, other tensile fabrics and other construction applications | Filtration and separation media | Removable covers for industrial process equipment | Medical applications | Technical textiles in transport vehicles |
| **Broader industrial uses** | Solvents | Catalysts | Processing aids | Ionic liquids | | |

**Table 3. Estimated annual tonnages from the use phase for PFAS manufacture and major PFAS use sectors in 2020 (low, mid and high estimates)[a]. Tonnages refer to PFASs used by manufacturers of PFAS-containing products in the relevant sector and to PFAS-containing products placed on the market (as substance on their own, in mixtures or articles), unless stated otherwise. Mid points are used in impact assessment.**

| **Application** | **PFAAs and PFAA precursors [t/y]** | | | **Fluorinated gases [t/y]** | | | **Polymeric PFASs [t/y]** | | | **Total PFASs[a] [t/y]** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Low | Mid | High | Low | Mid | High | Low | Mid | High | Low | Mid | High |
| Manufacture[b] | 53 902 | 85 977 | 118 051 | 4 330 | 7 107 | 9 883 | 40 000 | 67 500 | 95 000 | **98 232** | **160 584** | **222 934** |
| TULAC[c] | 6 998 | 17 911 | 28 824 | | | | 23 199 | 45 806 | 68 412 | **30 196** | **63 716** | **97 236** |
| Food contact materials and packaging | 828 | 2 896 | 4 963 | | | | 8 552 | 9 102 | 9 652 | **9 381** | **11 998** | **14 616** |
| Metal plating and manufacture of metal products | 0.4 | 153 | 305 | | | | 138 | 568 | 997 | **139** | **721** | **1 302** |

| **Application** | **PFAAs and PFAA precursors [t/y]** | | | **Fluorinated gases [t/y]** | | | **Polymeric PFASs [t/y]** | | | **Total PFASs[a] [t/y]** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Low | Mid | High | Low | Mid | High | Low | Mid | High | Low | Mid | High |
| Consumer mixtures and miscellaneous consumer articles | | | | | | | 10 | 55 | 100 | **31** | **81** | **130** |
| Cosmetics[d] | 366 | 366 | 366 | | | | | | | **366** | **398** | **430** |
| Ski wax | | | | | | | | | | **1.6** | **1.6** | **1.6** |
| Applications of fluorinated gases[e,f] | | | | *61 845* | *61 845* | *61 845* | | | | ***61 845*** | ***61 845*** | ***61 845*** |
| Medical devices | 800 | 800 | 800 | | | | 3 733 | 8 383 | 13 032 | **4 533** | **9 183** | **13 832** |
| Transport[e] | 2 | 12 | 21 | 28 618 | 28 624 | 28 630 | 6 972 | 13 669 | 20 365 | **35 585** | **42 290** | **48 996** |
| Electronics and semiconductors | 40 | 204 | 368 | 112 | 1 844 | 3 576 | 5 593 | 12 934 | 20 274 | **5 745** | **14 981** | **24 218** |
| Energy sector | 131 | 131 | 131 | | | | 2 231 | 5 367 | 8 503 | **2 362** | **5 497** | **8 634** |
| Construction products | 1 040 | 2 411 | 3 783 | | | | 4 500 | 10 434 | 16 369 | **5 540** | **12 846** | **20 152** |
| Lubricants | 104 | 104 | 105 | 12 | 13 | 14 | 3 972 | 6 288 | 8 604 | **4 089** | **6 406** | **8 722** |
| Petroleum and mining | | | | | | | | | | **4.4** | **7.0** | **9.5** |
| Printing applications | 11.5 | 63.3 | 115.5 | | | | 12.4 | 113.5 | 214.5 | **23.9** | **176.7** | **329.5** |
| Sealing applications | | | | | | | 20 000 | 22 725 | 25 450 | **20 000** | **22 725** | **25 450** |
| Machinery applications | | | | | | | 188 | 594 | 1 000 | **188** | **594** | **1 000** |
| Other medical applications | <<1 | <<1 | <<1 | 840 | 3 420 | 6 000 | 551 | 807 | 1 063 | **1 391** | **4 227** | **7 063** |
| Military applications[g] | | | | 999 | 999 | 999 | 817 | 1 128 | 1 438 | **1 816** | **2 127** | **2 437** |
| Explosives | | | | | | | 326 | 326 | 326 | **326** | **326** | **326** |
| Technical textiles | 187 | 727 | 1 267 | | | | 4 110 | 4 605 | 5 100 | **4 297** | **5 332** | **6 367** |
| Broader industrial uses | 36 | 200 | 363 | 189 | 1 040 | 1 891 | | | | **226** | **1 240** | **2 254** |
| **TOTAL (excl. manufacture)**[h] | **10 544** | **25 978** | **41 411** | **91 616** | **96 786** | **101 956** | **84 087** | **141 777** | **199 462** | **186 270** | **264 591** | **342 914** |

a) In some cases, a basis for providing a range is lacking. There the available estimate is applied throughout. The table only presents those values which are clearly attributable to specific PFAS groups. If volumes could not be clearly attributed to one PFAS group, the corresponding emissions are presented together with those that could be attributed under 'Total PFASs'. This can lead to the 'Total PFASs' column showing higher values than the sum of its different PFAS groups. Active substances (PPP, BP, MP) are not considered here because these substances are are already taken into account in their respective regulations, and concerns are addressed there;

b) The tonnage for "Manufacture" refers to the total volume of PFAS as substances on their own manufactured in the EEA.

c) TULAC = Textile, upholstery, leather, apparel and carpets;

d) The tonnage estimates for cosmetics include 366 tonnes of TFA from peptide synthesis discounted for 2020 from tonnages for 2023 (which is a PFAA) and 0.028-64.2 tonnes of various PFAS in cosmetic products. Due to limited information, no tonnages per sub-category of PFAS are specified for cosmetic products. Table A.116 in Annex A ranks the most frequently found PFASs in cosmetic products.

e) For these sectors the tonnages are the tonnages brought new to market and the tonnages brought to the market for refilling in 2020;

f) The tonnages do not include tonnages for fluorinated gases in transport sector;

g) Volumes reported for the sake of completeness, but not included in the total to avoid double counting as the uses are already covered in other sectors.

h) Total based on best available data (stock if available, new to market if stock is not available).

For a quick overview of the various sector contributions to the tonnages and emissions of total PFASs, see Table 4.

**Table 4. Tonnages and emissions of major use sectors and manufacture for 2020 (sorted by tonnage range)[a]**

| Application | Tonnage range | Emission range<br>[%] emitted in manufacturing and use phase | Contribution to total emission |
|---|---|---|---|
| Applications of fluorinated gases | 5 | 3 | 4 |
| Transport | 5 | 3 | 4 |
| Construction products | 5 | 3 | 2 |
| TULAC | 5 | 2 | 3 |
| Food contact materials and packaging | 5 | 2 | 1 |
| Manufacture | 5 | 1 | 1 |
| Sealing applications | 5 | 1 | 1 |
| Electronics and semiconductors | 5 | 1 | 1 |
| Other medical applications | 4 | 4 | 2 |
| Medical devices | 4 | 3 | 3 |
| Lubricants | 4 | 2 | 2 |
| Technical textiles | 4 | 2 | 1 |
| Military applications | 4 | 2 | 1 |
| Broader industrial uses | 4 | 2 | 1 |
| Energy sector | 4 | 1 | 1 |
| Cosmetics | 3 | 2 | 1 |
| Explosives | 3 | 2 | 1 |
| Metal plating and manufacture of metal products | 3 | 1 | 1 |
| Machinery applications | 3 | 1 | 1 |
| Printing applications | 3 | 1 | 1 |
| Consumer mixtures and miscellaneous consumer articles | 2 | 3 | 1 |
| Ski wax | 1 | 3 | 1 |
| Petroleum and mining | 1 | 2 | 1 |

| Table legend | | | | | |
|---|---|---|---|---|---|
| Tonnage range [t/y] | | Emission range [%] | | Emission contribution [%] | |
| 1 | 0 – 10 | 1 | 0 – 5 | 1 | 0 – 1 |
| 2 | 10 – 100 | 2 | 5 – 25 | 2 | 1 – 5 |
| 3 | 100 – 1 000 | 3 | 25 – 75 | 3 | 5 – 10 |
| 4 | 1 000 – 10 000 | 4 | 75 – 95 | 4 | 10 – 50 |
| 5 | >10 000 | 5 | >95 | 5 | >10 – 50 |

[a] Military applications reported for the sake of completeness, but not included when calculating totals to avoid double counting as the uses are already covered in other sectors.

## 1.3.2. **Manufacture and use – Market developments**

The baseline scenario is the situation in absence of the proposed restriction. This is not equal to the current situation as new legislation may affect the uses being proposed for restriction during the timeframe considered for analysis or annual use volumes might change (in comparison to the volumes for 2020 shown in Table 3) due to growth trends in manufacturing, PFAS use and import of PFASs. In this baseline chapter, the market growth rates as assumed for the baseline are summarised. The start year of the assessment is 2020, for which volume data is available to the Dossier Submitters. In Annex E, the baseline tonnage and emission estimates are projected for a time path of 30 years (2025-2055) for each assessed sector. These estimates are used in the Environmental Impact Assessment.

PFAS use volumes may not only grow due to market growth in existing markets but also due to development of new markets for which PFASs can be used. Identified potential markets, with a potentially strong growth potential, are the immersion cooling of datacentres, the cooling of electric cars, including the battery, during charging as well as oil fracking.

### 1.3.2.1. PFAS manufacturing

The baseline of manufacturing does not necessarily follow the combined baseline of uses as PFAS applications (e.g. cars and textiles) are of global relevance, with production also taking place in other parts of the world. As such, PFAS manufacture in the EU and EEA is not only dependent on downstream market developments in the EU and EEA but also other parts of the world.

As mentioned in Annex E.2.1.1., there is an expectation of market growth in the absence of regulatory action for all PFASs. While no specific data is available for PFAAs and PFAA precursors, there is an expectation of a global growth in demand from downstream uses related to the textile industry, which constitutes one of the most extensive users of non-polymeric PFASs. In the absence of other information, a steady growth of 2% per year is used by the Dossier Submitters. In relation to fluorinated gases, an annual decline of production of HFCs by 10% has been considered by the Dossier Submitters based on evidence pointing to a decline in the EU-28 production of HFCs due to the regulatory phase-down of HFCs and no known production of HFOs - the alternative to HFCs. For polymeric PFASs, the Dossier Submitters use a yearly growth rate of 6.5% as brought forward in the 2023 Annex XV consultation (#8521).

### 1.3.2.2. TULAC

The use of PFASs in TULAC is expected to increase. This is primarily driven by growth in the use of polymeric PFASs. Under the baseline scenario, it is assumed that usage of several PFAS groups (i.e. non-polymeric C2-C3 substances, C6 substances and other non-polymeric substances) in all TULAC uses grows at a standard steady 2% rate per year over the assessment period. The use of non-polymeric C4 substances in home textiles and consumer apparel is expected to be broadly static based on information from the call for evidence (CfE). Stakeholder interviews pointed to more demand in home textiles than consumer apparel, as a result of which the market growth in the baseline assumes an annual increase of 1% for home textiles and an annual decline of 1% for consumer apparel. The same trend is assumed for non-polymeric C5 substances. Non-polymeric C9-C14 substances will be restricted (under Regulation (EU) 2021/1297), so their use is expected to cease. The fluoropolymer market is expected to grow very strongly in the short to medium term (with assumed growth rates for different applications and periods ranging from 5% to 8%), but such strong growth is deemed unsustainable in the long term (with lower growth rates ranging between 1% and 2% being assumed after 2030). The use of side-chain fluorinated polymers is assumed to be static in the relation to consumer apparel due to growing awareness about its relevance as a source of emission of non-polymeric PFASs, while a steady growth rate of 2% is assumed for other textile applications. Some stakeholders responded in the consultation on the Annex XV report on policy proposals that might affect the growth rates (comment IDs #6395, 9291). The growth rate for estimating the baseline does not consider proposed policies and regulations that are still in the decision-making phase at the time of submission.

### 1.3.2.3. Food contact materials and packaging

For assessing the time path of PFAS use (tonnage) and emissions in food contact materials and packaging a mean real growth rate of 4% per year was assumed. This growth rate was derived from information about market growth rates in the following three specific sub-sectors (FoodDrinkEurope, 2019):

Packaging: Paper and board use in packaging has been relatively steady in the EU since 2015 (Cepi, 2020). In 2015, 38.95 million tonnes of paper were consumed in the EU by packaging, whilst in 2019, this figure had risen to 41.35 million tonnes, representing an annual growth rate of 1.5% per year. However, the single-use plastics directive could lead to much more moulded fibre being used, a PFAS impregnated technology.

Plastic packaging use is expected to grow strongly. Although PFASs have no function in the final product, for thermoplastic packaging extrusion PFASs are used as processing aid.

Non-stick surfaces in consumer cookware and domestic appliances: The global non-stick cookware market is estimated to be growing strongly at annual rates of around 6% (Grand View Research, 2021; IndustryARC, 2020).

In the industrial bakeware segment the assumption is that a growth of 1.5% is expected.

#### 1.3.2.4. Metal plating and manufacture of metal products

Information about growth rates is not available. Therefore, in metal plating a 0% growth rate per year is assumed.

#### 1.3.2.5. Consumer mixtures and miscellaneous consumer articles

For consumer mixtures, no generalised trends could be derived from available information due to stakeholder information including conflicting predictions. For the miscellaneous other consumer uses (identified during the consultation on the Annex XV report), no information on market trends is available. As such, a growth rate of 0% is assumed.

#### 1.3.2.6. Cosmetics

At European scale, a stable market is foreseen. This prediction is based on historic trends where there was no growth in market value in real terms in a three-year period ending in 2019. As such, a growth rate of 0% is assumed.

#### 1.3.2.7. Ski wax

For PFAS use in ski wax a market decline of 8% per year until 2030 and of 1% per year until 2040 is foreseen as there are already voluntary initiatives to reduce the use of PFAS-containing waxes. After 2040, the market of ski waxes is assumed not to decline any further.

#### 1.3.2.8. Applications of fluorinated gases

Information for different applications, generally suggests market growth. For commercial refrigeration, a yearly growth rate of 3% is, for example, assumed. The EU market for air conditioning has also seen strong growth over the last 25 years, originally in the commercial sectors, but such growth is now also taking place in the domestic sector. Over the next 30 years, demand in both sectors is expected to roughly double (IEA, 2018). Market data for fire suppressing agents suggests a strong growth over the period 2018 to 2025 at a compound annual growth rate of 5.9% (Frost & Sullivan, 2019). Projecting market growth at sector level is not possible with sufficient reliability. However, taking available information about market growth in different sub-sectors into account, a yearly real growth rate of 2% is assumed for the overall fluorinated gases sector.

#### 1.3.2.9. Medical devices

For the use of fluorinated gases as anaesthetics and contrast media an annual growth of 3 - 9% is foreseen based on commercial reports. The use of prescribed PFAS pharmaceuticals in the EU in 2019 is estimated by the Dossier Submitters to increase with 3.4% per year. Even though these examples are not medical devices, the Dossier Submitters assume that they are reasonable proxies for the growth of PFAS use in medical devices. Furthermore, positive growth rates are expected for fluoropolymer invasive use as well as medical packaging (mainly fluoropolymers). For other PFAS applications in this sector there is no reliable information about market trends. Taking available information about market growth in different sub-sectors into account, and the ageing population in Europe, a yearly real mean growth rate of 5% is assumed for the sector[11].

### 1.3.2.10. Transport

For assessing the time path of PFAS use (tonnage) and emissions in the transport sector a mean real growth rate of 1% per year is assumed. Though information about market trends is neither available at sector level, nor for specific PFAS uses within this sector, it seems likely that the market will further expand in the future.

### 1.3.2.11. Electronics and semiconductors

For assessing the time path of PFAS use (tonnages) in electronics, for different subsectors different growth rates are assumed. Table 5 summarised the different growth rates mentioned in the stakeholder consultation and in relevant literature. Based on the tonnages in the baseline, the overall growth rate used for this sector is estimated. As new technology emerges, and the world becomes more digitalized a higher demand for electronics and semiconductors is expected.

Table: Tonnages new on the market, procentual distrusted over the subsectors and growth rates per sub-sector

**Table 5 Tonnages new on the market, procentual distrusted over the subsectors and growth rates per sub-sector**

| | **Tonnage distribution** | **2020-2030** | **2031-2040** | **After 2040** |
|---|---|---|---|---|
| Electronics in general | 72% | 6% | 6% | 6% |
| Semiconductors | 2% | 8% | 6% | 6% |
| Immersion cooling | 9% | 27% | 6% | 6% |
| Thermal management systems | 8% | 16% | 6% | 6% |
| Sensors (incl. PCB) | 6% | 8% | 6% | 6% |
| Anti-drip agent | 4% | 7.8% | 6% | 6% |
| Photonics | 0% | 7% | 6% | 6% |
| **E&S sector Average** | | 11.14% | 6% | 6% |

Source: stakeholder input and own calculations

### 1.3.2.12. Energy sector

For PFAS uses in the energy sector, an annual growth rate of 34% is assumed from 2020-2030 and 9.5% for 2030-2050. Overall, most growth estimates are based on EU initiatives such as the Green deal and REPowerEU. These initiatives will lead to growth in use of PFASs because of their increasing application in fuel cells and hydrogen technology, rechargeable batteries, photovoltaic cells and wind turbines. In general, it can be concluded that for at least some of the uses (e.g. fuel cells, lithium-ion batteries and photovoltaic cells) a significant growth of PFAS use in this sector is expected because of the European Green Deal ambitions. JRC as well as important stakeholders in the industry estimate that the EU production of lithium-ion batteries will increase strongly until 2030. Additionally, an increase in the use of PFASs to be used in PEM electrolysis technology (proton exchange membrane – a fuel cell) is foreseen to accomplish the 2030 EU hydrogen Strategy goal of 40 GW / 120 GW goal of REPowerEU electrolysis capacity within the EU.

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[11] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Ageing_Europe_-_statistics_on_population_developments, date of access: 2023-01-05.

#### 1.3.2.13. Construction products

For the baseline scenario of PFAS use and emissions in the construction sector a declining growth rate is assumed. Projecting market growth at sector level is not possible with sufficient reliability. However, taking available information about market growth in different sub-sectors into account, a yearly real growth rate of 1% is assumed for the overall construction sector.

#### 1.3.2.14. Lubricants

For PFAS-based lubricants an annual growth rate of 5% is assumed between 2020 and 2030, after which it is assumed to slow due to market saturation, increasing thereafter at 2.5% annually to 2040 and 1% annually after 2040. The future projections do not include any consideration of changes in usage (increase, decrease or replacement) as a result of changes in technology. Likewise, the projections do not consider changes in abatement technology which may affect emissions.

#### 1.3.2.15. Petroleum and mining

Precise growth rates for PFAS use in petroleum and mining are not known. According to a recent report NEA (2021), PFAS use in petroleum and mining can be expected to decline significantly in the coming decades. Furthermore, the oil and gas infrastructure is expected to become increasingly decommissioned, with over 200 platforms to be partially or fully removed, and over 2 500 wells to be decommissioned in the North Sea before 2030. However, input from manufacturers and suppliers has indicated that the demand for PFAS-based tracer and anti-foaming agents is expected to increase in future years, as the industry is likely to explore more 'challenging' environments for oil and gas production. In the absence of more detailed information or estimates from industry, an annual growth rate of 1% has been assumed for the three product categories (PFAS-based tracers, antifoaming agents, solid fluoropolymers).

#### 1.3.2.16. Printing applications

Using volumetric market forecast estimates, and assuming no significant external market influences, it can be inferred that PFAS use in printing applications will continue to grow. The use volume of PFAS in printing applications was estimated based on a low and high range of values provided by respondents to the consultation on the Annex XV report as presented in Annex A. To forecast growth, an average Compound Annual Growth Rate (CAGR) of 6.5% was identified from several market data sources up to 2028[12]. This corresponds to a linear annual growth rate of 8.2% relative to 2020 which was applied to these estimates, as this is deemed by Dossier Submitters to be a more realistic representation of long-term growth up to 2070 than a CAGR.

#### 1.3.2.17. Sealing applications

A growth rate of 3% is assumed for the market of sealing applications. Several growth rate predictions for single companies and for specific sectors have been identified in the comments on the consultation on the Annex XV report, ranging from around one to several hundreds of percent. The comments indicate though that the growth rate for the sealing producing sector is closer to one. To account for the probability of specific sectors (on the demand side)

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[12] https://www.inkwoodresearch.com/reports/europe-digital-textile-printing-inks-market/#:~:text=The%20Europe%20digital%20textile%20printing%20inks%20market%20is,the%20development%20of%20the%20textile%20and%20garment%20industry and https://www.tritonmarketresearch.com/reports/europe-digital-inks-market, date of access for both: 2024-11-29.

affecting the growth of sealing producers, the growth rate has been set slightly higher than what is expected for sealing producers.

#### 1.3.2.18. Machinery applications

A growth rate of 3% is assumed for the market of machinery applications based on its similarity to the market for sealing applications.

#### 1.3.2.19. Other medical applications

For assessing the time path of PFAS use (tonnages) in sealing aplications, different growth rates are found in the literature. The volumes of PFAS f-gases used as propellants in pMDIs are assumed to be halved between 2025 and 2035 (which corresponds to a yearly growth rate of -7.4%), and will remain stable before and after this period (growth rate is 0%). For the other uses assessed in this sector, the Dossier Submitters assume a growth rate of 5% per year. These assumptions lead to the following compiled baseline growth rates for the sector as a whole: 2020-2025: 0.95% per year; 2025-2035: -5% per year; after 2035: 0.95% per year.

#### 1.3.2.20. Military Applications

It is assumed that market growth between 2020 and 2027 will follow a similar trend to that from 2020-2024, and that it will decrease to the average between 2005 and 2024 after 2027. Therefore, the estimates by the Dossier Submitters are extrapolated using a market growth rate of 11.57% between 2020 and 2027, and of 4.89% after 2027

#### 1.3.2.21. Explosives

A growth rate of 3.7% is assumed for the market of explosives based on the most appropriate data available to the Dossier Submitters in market reports representing explosives used for industrial applications in Europe.

#### 1.3.2.22. Technical textiles

The use of PFASs in technical textiles (and, in some cases, comparable non-textile applications[13]) is expected to increase in line with general market developments. While technical textile applications are diverse, detailed information reporting the use of PFASs was only identified and/or provided for:

- Outdoor technical textiles;
- Architectural membranes, other tensile fabrics and other construction applications;
- Filtration and separation media;
- Removable covers for industrial process equipment;
- Medical applications; and
- Technical textiles for transport vehicles.

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[13] Some of the PFAS-containing/-based filtration and separation media as well as construction applications are not a textile by definition. Examples are porous membranes "*formed by phase transition processes and consist[ing] of a continuous polymer layer/sheet with pores in it*" used for filtration purposes (comment ID #7099) and the use of ETFE film/foil as load-bearing architectural elements. Similarly, some articles covered under 'medical applications', e.g. some single-use gowns, might not be textiles by definition. Relevant textile and non-textile uses are nevertheless assessed together to enable a meaningful and simultaneous comparison with non-PFAS alternatives.

Some stakeholders highlighted in the consultation on the Annex XV report that other legislative actions, such as a restriction on PFHxA, its salts and related substances, (could) affect growth rates. The Dossier Submitters note that Commission Regulation (EU) 2024/2462[14] of 19 September 2024 restricting the use of PFHxA, its salts and related substances indeed restricts the use of PFHxA, its salts and related substances in (i) textiles, leather, furs and hides in clothing and related accessories for the general public as well as (ii) footwear for the general public by 10 October 2026. The use of these substances in textiles, leather, furs and hides in uses other than in clothing and related accessories for the general public is furthermore prohibited from 10 October 2027. However, textiles used as construction textiles are explicitly excluded from the restriction. The Dossier Submitters therefore consider that the use of PFHxA and related substances will indeed decline in relation to outdoor technical textiles, while its use in the other applications remains unaffected. Nevertheless, it should be noted that some of the uses assessed under TULAC (see Annex E.2.2), i.e. home textiles, consumer apparel and leather, are equally affected. At the time of the update of the Background Document for TULAC based on information submitted to the consultation on the Annex XV report (April 2024), the PFHxA restriction was not yet decided. Therefore, the impact of the PFHxA restriction on the baseline was not taken into account as the assessment of the Dossier Submitters by default does not consider proposed policies and regulation that have not yet entered into legal force. To maintain consistency in considered regulations across the dossier, the PFHxA restriction and its impact on the use of PFHxA in technical textiles is therefore also not accounted for in the baseline for technical textiles. It can furthermore not be ruled out that C6 substances used in relation to outdoor technical textiles would be substituted with other PFASs, e.g. C4-based treatments or fluoropolymer coatings. This possible shift is also not accounted for.

The assumed annual growth rates for all sub-uses, developed based on information from KPMG (2021) and information from the consultation on the Annex XV report (in relation to outdoor technical textiles) are summarised in Table 6. For more details on the underlying considerations, please refer to Annex E.2.22.1.

**Table 6. Assumed annual growth rates, per use of PFAS in technical textiles.**

| | **Assumed linear growth rate** | |
|---|---|---|
| **Outdoor technical textiles** | 2020-2032 | 6.6% |
| | 2032 onwards | 4.9% |
| **Architectural membranes, other tensile fabrics and other construction applications** | 2020-2032 | 6.8% |
| | 2032 onwards | 5.1% |
| **Filtration and separation media** | 2020-2032 | 7.6% |
| | 2032 onwards | 5.7% |
| **Removable covers for industrial process equipment** | 2020-2032 | 6.4% |
| | 2032 onwards | 4.8% |
| **Medical applications** | 2020-2032 | 6.8% |
| | 2032 onwards | 5.1% |
| **Technical textiles for transport vehicles** | 2020-2032 | 5.3% |
| | 2032 onwards | 4.0% |

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[14] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202402462, date of access: 2025-05-27.

A weighted average of the above growth rates is ultimately used for estimating the amount of PFAS used during the analytical period, i.e. a linear growth rate of 6.4% between 2020 and 2032 and a linear growth rate of 4.8% after 2032.

### 1.3.2.23. Broader industrial uses

For the market growth for uses falling under broader industrial uses, no specific non-confidential information was submitted in the Annex XV consultation. Therefore, the growth rate is based on the growth rates used in closely related sectors, being transport, electronics and semiconductors, applications of fluorinated gases, machinery applications, sealing applications, and lubricants, combined with general information on expected global market developments from market analyses. Based on this combined information, the estimated growth rate for broader industrial uses was approximately 3%. This growth rate is used for further assessments.

# 2. Impact assessment

## 2.1. Introduction

The impact assessment in this restriction proposal is prepared to demonstrate whether the restriction is the most appropriate Risk Management option (RMO) to control the risks; and to identify which of the restriction options (ROs) is the best option.

Impacts comprise both positive (benefits) and negative impacts (costs) of different ROs in comparison to the baseline scenario. Benefits of restriction options comprise benefits for the environment, and for human health. Environmental benefits are expressed as the expected total amount of emissions avoided over a defined time period (30 years). Benefits to human health are evaluated qualitatively as data is limited, or missing, to assess (i) the hazard of many of the individual PFASs; (ii) the associated thresholds below which exposure is not expected to lead to adverse health effects, if such limits exist, and (iii) the prediction of future human exposure levels.

Costs of ROs comprise different components, for example costs to industry in the form of producer surplus losses resulting from business closures or substitution, whereby producer surplus losses resulting from business closures can in some cases be offset by producer surplus gains of companies that are already supplying alternative-based products and can take over the market shares of companies ceasing operation. Where with a high share of business closures is expected and the offsetting potential is deemed to be limited, producer surplus losses might also be incurred by companies in the upstream supply chain. Further possible costs include consumer surplus losses as a result of changes to the product price, welfare losses and/or costs resulting from changes in the characteristics of goods, e.g. their quality and lifetime, welfare losses resulting from the absence of the product (where substitution is not feasible) as well as job losses. In most cases, these costs are assessed qualitatively due to insufficient data. In addition to the benefits and costs mentioned above, restriction options can impact future remediation or decontamination costs associated with contaminated watersheds used as supply for drinking water production and contaminated soils.

## 2.2. Regulatory risk management options

In response to the identification of the risk related to the use of PFASs, the Dossier Submitters have conducted an analysis of various regulatory risk management options (RMOs) to identify the most appropriate option for addressing the identified risks, including various permutations of a REACH restriction[15]. As explained in section 1.1.2, the common concern (persistence) regarding PFASs should be addressed via a group approach to prevent regrettable substitution.

For information purposes, in section 2.2.1 a (non-exhaustive) overview of current relevant regulatory measures is given.

Additional different European regulatory measures are shortly discussed in section 2.2.2. It is concluded that measures in different EU legislation could be taken to manage risks and some of them could be considered as complementary to a REACH restriction. Many RMOs directly related to REACH processes are not considered manageable for the whole group of PFASs. This is the case for CLH, SVHC identification and authorisation. For particular (groups of) PFASs harmonised classification and labelling and authorisation could be taken into consideration as is current practice. A REACH restriction is considered the most effective tool to manage the risk from substances, such as PFASs, with a widespread use in industrial processes but also in products placed on the market for use by professionals and consumers.

Finally, in section 2.2.3 the use of PFASs as active substances in Plant Protection Products (PPP), Biocidal Products (BP) and Medicinal Products (MP) is discussed.

### 2.2.1. **Overview of current regulatory measures**

#### 2.2.1.1. Stockholm Convention and POP Regulation

The Stockholm Convention is an international treaty aiming to eliminate or restrict the production and use of Persistent Organic Pollutants (POPs) in order to protect human health and the environment from those chemicals. POPs are considered chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in humans and wildlife, and have harmful impacts on human health or on the environment.

The Stockholm Convention (UNEP, 2018) is implemented in the EU via the POP Regulation (Regulation (EC) 2019/1021). PFOS and PFOA are restricted in the Stockholm Convention. In 2022, also perfluorohexane sulfonic acid (PFHxS), its salts and related substances have been included in the Stockholm Convention.

Even before the EU REACH Regulation came into force, an EU-wide ban on PFOS (perfluorooctane sulphonic acid, C8 PFSAs) was agreed (see EC Directive 2006/122), which was shortly afterwards incorporated into the EU POP Regulation in order to take over the corresponding regulation from the international Stockholm Convention (Regulation (EU) 757/2010). Therefore, the REACH restriction entry for PFOS was deleted (see EU Regulation 207/2011). The Stockholm convention for PFOS covers: "PFOS, salts and perfluorooctane sulfonyl fluoride". In the EU POP Regulation the definition of the scope is "Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, metal salt (O-M+), halide, amide, and other derivatives including polymers)". Therefore, also derivatives (related substances that can degrade to PFOS) are covered in both the POP convention and EU POP Regulation. In 2019, the PFOS ban under the Stockholm Convention was re-examined and all exemptions granted in the EU until then were deleted, except for the use of PFOS as

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[15] https://echa.europa.eu/documents/10162/a59647fb-fcc5-869b-10d4-c14258bbea1d, date of access: 2023-01-05.

a spray suppressant for non-decorative hard chrome plating (chromium VI) in closed loop systems.

#### 2.2.1.2. REACH Regulation

Under REACH, PFOA, its salts and related substances (i.e. substances that can degrade to PFOA) are restricted with certain derogations within the EU as of 4 July 2020. In May 2019, PFOA, its salts and PFOA-related compounds were included into Annex A of the Stockholm Convention. Therefore, the inclusion of PFOA in the EU POP Regulation was also being prepared and also took place by inclusion into Annex I of the POP Regulation in April 2020[16]. This overrides the REACH restriction - and thus also the applications and deadlines regulated therein. The Annex XV entry for PFOA in REACH (entry 68) has recently been deleted (amended by Regulation (EU) 2020/2096 of 15 December 2020). It should be noted that the exemptions granted under the Stockholm Convention are not exactly the same as before under REACH.

The following PFAS restrictions and SVHC dossiers have been handled under REACH so far.

Restriction:

2006 – PFOS ban (restriction moved to EU POP Regulation)

2019 –TDFAs in solvent-based spray applications (Annex XVII entry 73)

2020 – PFOA, salts and related substances ban (restriction moved to EU POP Regulation)

2021 – C9-C14 PFCAs (Annex XVII entry 68)

2021– PFHxS and related substances (recently included in EU POP Regulation)

2024 – PFHxA salts and related substances (Annex XVII entry 79)

2025 – Aqueous firefighting foams (decision making)

SVHC identification:

2012 - C11-C14 PFCAs listed as very persistent and very bioaccumulative (vPvB)

2013 – C8 PFCA (PFOA + Salts) listed as persistent, bioaccumulative and toxic (PBT)

2015 – C9 PFCA (PFNA + Ammonium & Na salts) listed as PBT

2016 - C10 PFCA (PFDA + Ammonium & Na salts) listed as PBT

2017 - C6 PFSA (PFHxS + Salts) listed as vPvB

2019 - 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides listed as Persistent Mobile and Toxic (Equivalent Level of Concern (ELoC))

2020 – C4 PFSA (PFBS + Salts) listed as ELoC

2022 - Perfluoroheptanoic acid (PFHpA) + its salts listed as PBT, vPvB, ELoC

2023 - reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine listed as vPvB

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[16] Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council.

2025 – Perfluamine listed as vPvB

### 2.2.1.3. Montreal Protocol

The Montreal Protocol on Substances that Deplete the Ozone Layer is a landmark multilateral environmental agreement on substances that deplete the ozone layer that regulates nearly 100 man-made chemicals referred to as ozone depleting substances (ODS). The protocol regulates production, import, export and to some degree destruction of ODS. When released to the atmosphere, those chemicals damage the stratospheric ozone layer, earth's protective shield that protects humans and the environment from harmful levels of ultraviolet (UV) radiation from the sun. Adopted on 15 September 1987, the protocol is to date the only UN treaty that has been ratified by every country on earth - all UN Member States.

The Montreal Protocol predominantly covers CFCs and HCFCs ranging from C1-C3 as core, and being partly or fully halogenated. Hydrochlorofluorocarbons (HCFCs) are gases used worldwide in refrigeration, air-conditioning and foam applications, but they are being phased out under the Montreal Protocol. HCFCs are both ozone depleting substances and powerful greenhouse gases: The most commonly used HCFC is nearly 2 000 times more potent than carbon dioxide in terms of its global warming potential (GWP).

In Europe, the Protocol is implemented through EU-wide legislation that not only meets the Protocol's objectives but also contains stricter, more ambitious measures - the most recent in the Regulation (EU) 2024/590 on substances that deplete the ozone layer. While the Montreal Protocol regulates the *production* of ozone depleting substances and their *trade* in bulk, the EU Regulation prohibits their *use* in most cases (certain uses are still permitted in the EU). Moreover, it regulates not only substances in bulk, but also those contained in products and equipment. Almost all uses of ODS are now phased out in Europe.Substances that are used as process agents are derogated from the restrictions, and substances such as chlorofluorocarbon 113 (CFC 113) and hydrochlorofluorocarbon 22 (HCFC 22), which are used as intermediates in the production of fluoropolymers, are not phased out. These substances are not covered by this restriction proposal either, since they are not fulfilling the PFAS definition.

A complete list of ozone depleting substances and the products and equipment in which these may be present is provided in EC (2016). The CFCs, Halons or HCFCs, among other substances, all contain chlorine or bromine.

As of 2016, the Kigali amendment to the Montreal Protocol regulates the consumption and production of HFCs to gradually reduce the consumption and production of HFCs. Like the Protocol itself, it is a legally binding agreement designed to create rights and obligations in international law.

HFCs were used to replace the substances banned in the Montreal Protocol because they have zero impact on the ozone layer. However, HFCs are powerful greenhouse gases that contribute to climate change, so this Kigali amendment adds HFCs to the list of chemicals that countries promise to phase down.

As of July 1, 2024, 159 states and the European Union have ratified the Kigali Amendment.

### 2.2.1.4. Regulations of fluorinated gases

Regulation (EU) 2024/573 (F-Gas Regulation)

In addition to the regulation with respect to ODS, there is a specific regulation on fluorinated greenhouse gases. Since the mid-1990s the ODS have been substituted by certain fluorinated greenhouse gases (F-gases), in particular hydrofluorocarbons (HFCs). The new current F-gas Regulation (Regulation (EU) 2024/573) applies since 12 March 2024 when it replaced the revised F-gas Regulation from 2015, (which again replaced the original F-gas Regulation adopted in 2006). The F-Gas Regulation aims to reduce F-gas emissions (measured as $CO_2$ equivalents) from multiple uses. There are five key measures[17] of the new F-gas regulation:

1. Reducing production and import of hydrofluorocarbons: The quota system generates a steeper reduction in the amounts that importers and producers may place on the EU market, and in 2050, HFCs will be phased out in the EU.
2. Expanding the scope of the quota system: HFCs used in metered dose inhalers have been integrated into the quota system. Additional prohibitions on F-gas equipment, products and use of F-gases will apply in the future.
3. Stricter rules to prevent emissions: The Regulation covers additional equipment and gases, expanding measures to prevent leakage during transportation, installation, servicing, and disposal of equipment and products.
4. Facilitating better monitoring: More digitalisation and electronic automation of custom control will allow enhanced enforcement and monitoring in the Member States and combat illegal trade.
5. Capping EU production of HFCs: Starting in 2025, producers will receive rights equivalent to 60% of their average annual production from 2011 to 2013. This rate will decline to 15% by 2036.

Annex I section I to the F-gas regulation lists a number of HFCs, whereas section 2 lists a number of PFCs. Annex II lists HFOs/HCFOs and fluorinated substances used as inhalation anaesthetics. Annex III contains a list of fluorinated ethers, ketones and alcohols. To a large extent there is overlap between the substances specified in the F-gas regulation and the chemical scope of the PFAS restriction proposal.

In Annex IV there is a list of prohibitions on placing on the market of different F-gases in specific equipment. In many cases, these prohibitions are linked to specific groups of F-gases, such as HFCs, and F-gases that have a GWP above a certain threshold. However, in other cases the prohibitions are broader.

Directive 2006/40/EC (MAC Directive)

The Mobile Air-Conditioning (MAC) Directive (EC, 2006) prohibits the use of F-gases with a GWP of more than 150 in new types of cars and vans introduced from 2011, and in all new cars and vans produced from 2017.

The traditionally used refrigerant in MAC systems, HFC-134a ($CH_2FCF_3$), has a GWP of 1 430 and hence has been phased out for use in air condition equipment in new cars in the EU. The Directive does not specify any particular refrigerant or system, leaving the technical choice on the car manufacturers.

The MAC Directive is limited to the use of fluorinated gases in air-conditioning systems in cars and vans, but not in buses, trains, ships etc. Air condition equipment is only one of several applications of fluorinated gases.

Both, the F-gas Regulation and the MAC Directive already address applications of certain fluorinated gases, i.e. by requiring substitution to lower GWP F-gases or, in certain uses, to non-fluorinated substances as well as introducing requirements for minimising releases of F-gases during their complete lifecycle and reporting. However, these regulations primarily target the GWP of F-gases, while the risks that have been identified in this restriction proposal, i.e., those associated with the formation of very persistent degradation products (e.g. TFA) in the environment, are not addressed. Therefore, it is appropriate to explore whether existing legislation for F-gases, such as the F-gas Regulation and the MAC Directive remains

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[17] https://climate.ec.europa.eu/eu-action/fluorinated-greenhouse-gases/eu-rules_en, date of access: 2024-07-03.

appropriate to control these other identified risks or whether additional, complimentary, risk management is also justified.

The atmospheric degradation of fluorinated gases is known to form persistent PFAS degradation products, like TFA, that dissolve in water and are transferred to the terrestrial and aquatic compartments via precipitation (rain and snow). Today increasing concentrations of these substances in freshwater and the terrestrial environment are found. TFA has a harmonized classification H412 "harmful to aquatic life with long lasting effects" (Aquatic Chronic 3), while other relevant substances may have similar concerns. An intention to classify TFA as Acute Tox. 3, Skin Corr. 1A, Repr. 1B, Aquatic Chronic 3, PMT, and vPvM has been notified to ECHA.[18] Degradation of fluorinated gases in the atmosphere is assessed in section B.4.1.3.2.

The aim of the F-gas Regulation is a gradual phase-down of the F-gases' total contribution to global warming. With this as the main objective, it is convenient and common in relation to the regulation to measure use and emission volumes in $CO_2$-equivalents based on the individual gases' GWP value – rather than to measure volumes in metric tonnes or similar. A transition from high GWP gases to low GWP gases will translate into a decrease of the F-gases' total contribution to global warming, but it will not necessarily lead to a decrease of the overall use and emission volumes in tonnes. When considering degradation of fluorinated gases in the atmosphere to persistent PFAS degradation products, it is the volumes as measured in tonnes/year that are important, as it is in the end the mass of these substances in the environment that is the relevant measure. Hence, the trend in use and emission volumes observed for fluorinated gases as measured in $CO_2$-equivalents may be misleading when considering the concern of persistent degradation products in the environment.

Furthermore, the F-gas Regulation and MAC Directive primarily target fluorinated gases above a determined threshold (the lowest being GWP 150). This means that F-gases with a lower GWP-value (e.g. HFOs) are only affected by the regulations to a limited extent. However, in many cases the low GWP fluorinated gases have the highest potential to form persistent substances like TFA in the environment. This applies to e.g. several of the HFO's which are currently on the rise, e.g. in the MAC sector, where leakage rates are substantial. Some of the HFO's are rapidly transformed into 100% TFA in the atmosphere.

The future development of EU-27 emissions of HFO-1234yf in the period 2020 – 2050 was assessed in the impact assessment report for the new F-gas Regulation,[19] under the baseline as well as phase-down options 1, 2 and 3,[20] see Figure 6. It is evident that under all phase-down options considered, emissions of HFO-1234yf will increase sharply until they level out, or increase further, albeit at a lower rate. No reduction of emissions is envisaged.

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[18] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e188e6e587, date of access: 2024-07-03.

[19] https://eur-lex.europa.eu/resource.html?uri=cellar:10680588-b5a0-11ec-b6f4-01aa75ed71a1.0001.02/DOC_2&format=PDF, date of access: 2024-07-03.

[20] Option 1: Steps included after 2030 simply to ensure long-term compliance with the HFC consumption schedule of the Protocol under all circumstances; Option 2: Steeper phase-down assuming replacement at proportionate costs; Option 3: Steepest phase-down based on maximum replacement of high GWP HFCs as soon as it is technically possible.

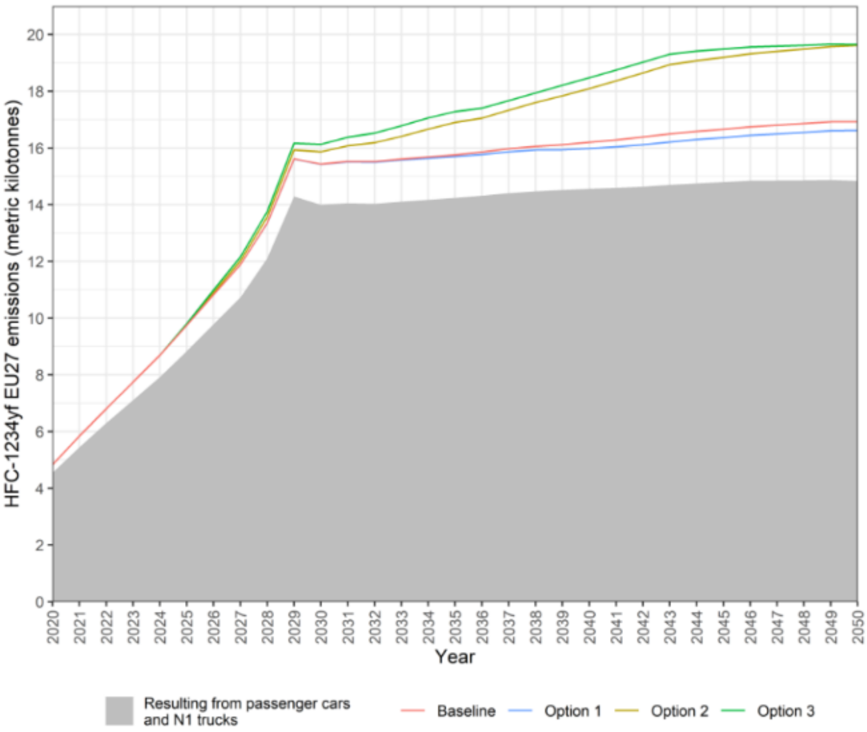

**Figure 6. Future development of HFO-1234yf emissions under the F-gas regulation phase-down options (Reproduced from impact assessment, Figure 31).**

### 2.2.1.5. Drinking Water Directive (Directive (EU) 2020/2184)

The recast of the Drinking Water Directive, which took effect on 12 January 2021, sets limit values of 0.1 µg/L for the sum of 20 individual PFAAs (C4-C13 PFCAs and C4-C13 PFSAs) and 0.5 µg/L for the total PFAS concentration in water for human consumption (EC, 2020b).

### 2.2.1.6. Water Framework Directive (Directive 2000/60/EC)

PFOA and PFOS are priority hazardous substances under the Water Framework Directive, meaning that countries monitor the presence of these substances in lakes, rivers, groundwater and coastal waters.

### 2.2.1.7. Cosmetic Product Regulation (Regulation (EC) No. 1223/2009)

The Cosmetic Product Regulation includes and prohibits the use of PFOS and its potassium, ammonium, and lithium salts, PFOA, PFNA and its sodium, and ammonium salts, diethanolaminperfluoroctansulfonate and PFHpA in cosmetic products. All of them have a Repr. Cat. 1B classification.

In general, CMR substances in category 1 are prohibited in cosmetics (there are special exception rules that might allow them to be used), and CMR substances in category 2 can be used if the Scientific Committee on Consumer Safety (SCCS) has evaluated them and deemed them safe to be used (often with a specified concentration limit). For other substances, a quantitative risk assessment is carried out, looking at effect levels and exposure (incl. skin absorption). It is very rare for a substance to be considered to pose a risk from use in cosmetics (except from skin sensitisers, but that does not include PFASs as far as the Dossier Submitters are aware).

The Cosmetic Product Regulation only takes health and not the environment into account. Therefore, the Dossier Submitters cannot see that this regulation could offer the same protection as a broad PFAS restriction, which is largely based on environmental arguments.

The Dossier Submitters find it difficult to see that the Cosmetic Product Regulation could control the risks of PFASs. A substantial amount of data would need to be generated, and they would need to be given a CMR 1/2 classification to be banned or reviewed by SCCS. It is unreasonable, in the same way that the Dossier Submitters would CLH-evaluate/classify all PFASs. In such cases, it would require a group entry in the Cosmetic Product Regulation (if that is possible).

#### 2.2.1.8. Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

According to Article 5 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, specific measures for certain groups of materials or articles can be established. The regulation would allow to regulate the use of PFASs in or their migration from food contact materials (e.g. paper, rubber, coatings) (i.e. only be allowed below a certain limit value).

In this context Regulation (EU) No 10/2011 regulates food contact materials made of plastics. Only substances listed in Annex I of this regulation are allowed to be used as monomers or additives for plastic food contact materials. For PFOA and its salts a concentration limit of 25 µg and for their precursors a concentration limit 1 000 µg applies. Nevertheless, the ammonium salt of PFOA is still allowed to be used in the production of reusable articles manufactured at high temperatures (sintered). The release of relevant amounts of PFOA from such articles into food is not expected.

#### 2.2.1.9. Examples of legislation outside the EU

USA

Detection of some PFAS—primarily PFOA and PFOS in numerous locations and multiple media across the US have prompted calls for increased federal action and authority to prevent and mitigate releases of and exposures to PFAS.

Federal actions to address potential risks from PFAS have focused mostly on PFOS and PFOA because of past uses, prevalence in the environment, and availability of health effects research. These actions have been taken primarily under the authorities of the Toxic Substances Control Act (TSCA); the Safe Drinking Water Act (SDWA); the Clean Water Act (CWA); and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and related Department of Defense (DOD) response authorities. The U.S. Environmental Protection Agency (EPA) has used various authorities to address PFAS in commerce, public water supplies, surface waters, and in the environment.

Under TSCA, EPA has taken actions to gather and assess existing information on the risks of PFOS, PFOA, and certain other PFAS. The agency has required manufacturers to develop new information to evaluate risks of various PFAS and has issued orders restricting their manufacture, processing, distribution, use, and/or disposal pending the development of new risk information. EPA worked with U.S. manufacturers as they voluntarily phased out production of PFOS, PFOA, and related substances. Under SDWA, EPA determined to regulate PFOA and PFOS in public water supplies in March 2021. The act requires EPA to propose a regulation within 24 months of finalizing a regulatory determination (e.g. by March 2023 for PFOA and PFOS), and finalize the regulation within 18 months of publishing the proposal. Under CWA, EPA has several authorities it may use to address PFAS in surface waters. To date, EPA has not published final limitations for any PFAS, but has taken steps toward doing so. EPA has, in specific instances, used permit authorities to address PFAS concerns at facilities that discharge to surface waters.

DOD and other federal agencies have used CERCLA authorities to respond to releases of various PFAS at federal facilities, although such responses are not statutorily required. DOD administers the vast majority of federal facilities where PFAS have been detected. DOD has been responding to releases of PFOA and PFOS from the use of AFFF at active and decommissioned U.S. military installations under the Defense Environmental Restoration

Program. DOD has been phasing out the use of AFFF that contains PFOA or PFOS to reduce the risks of future releases.

Several federal agencies, including EPA and the Agency for Toxic Substances and Disease Registry (ATSDR), have been evaluating potential health effects that may be associated with exposures to various PFAS. The U.S. Food and Drug Administration and the U.S. Department of Agriculture are addressing risks of PFAS in dairy milk, other foods, and food contact applications.On October 18, 2021 the PFAS Strategic Roadmap was announced: EPA's Commitments to Action 2021-2024 (EPA-US, 2021b). The roadmap sets timelines by which EPA plans to take specific actions and commits to bolder new policies to safeguard public health, protect the environment, and hold polluters accountable. The actions described in the PFAS Roadmap each represent important and meaningful steps to safeguard communities from PFAS contamination. Cumulatively, these actions will build upon one another and lead to more enduring and protective solutions.

With the National Defense Authorization Act, 2019, the Pentagon has been restricted from purchasing fluorinated fire-fighting foams (FFF) after 2022, and prohibited from using FFF after 2023.

In the 117th US Congress, more than 60 bills have been introduced that would address PFAS through various federal agencies and authorities. Two of these bills have been enacted. Division J, Title VI of the Infrastructure Investment and Jobs Act[21] (IIJA; P.L. 117-58), enacted in November 2021, provides a total of $5 billion in emergency appropriations to EPA from FY2022 through FY2026 to address emerging contaminants (that may include PFAS) in wastewater and drinking water. The National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (NDAA FY2022; P.L. 117-81), enacted in December 2021, includes several provisions related to PFAS that build upon certain requirements enacted in prior NDAAs[22].

Multiple bills were enacted in the 115th Congress and 116th Congress that included provisions related to PFAS among other purposes. Some of these provisions are similar in scope or objective to other bills introduced as stand-alone measures. The NDAAs enacted for FY2018 through FY2021 included numerous PFAS provisions that directed DOD to investigate and remediate PFAS contamination at U.S. military installations and National Guard facilities, restrict the use of AFFF and certain other products containing PFAS, transition to alternative firefighting foams that do not contain PFAS, and take other related actions. Some of the NDAA provisions also directed EPA, CDC, ATSDR, U.S. Geological Survey (USGS), and other federal agencies to take additional actions to address PFAS. The FAA Reauthorization Act[23] of 2018 (P.L. 115-254) also allowed the use of fluorine-free firefighting foams for civilian airport certification, and the 2018 "Farm Bill" (P.L. 115-334) authorized technical assistance for rural water systems to address PFAS[24].

Further summary on relevant federal legislation in the US regarding the response to risks from PFAS is listed on the site of the US Congress[25].

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[21] https://www.congress.gov/bill/117th-congress/house-bill/3684/text, date of access: 2025-05-15.

[22] https://www.congress.gov/bill/117th-congress/senate-bill/1605/text, date of access: 2025-05-15.

[23] https://www.congress.gov/bill/115th-congress/house-bill/302/text, date of access: 2025-05-15.

[24] https://www.congress.gov/bill/115th-congress/house-bill/2/text, date of access: 2025-05-15.

[25] https://www.congress.gov/crs-product/R45986, date of access: 2025-05-15.

The list of proposed stand-alone PFAS legislation divides into four key elements. These elements include: (1) enhanced detection and research; (2) new regulatory mandates; (3) cleanup assistance; and (4) exposure to PFAS contamination at or near military installations.

Figure 7 documents publicly known PFAS pollution in public water systems and military bases, airports, industrial plants and dumps, and firefighter training sites in the US.

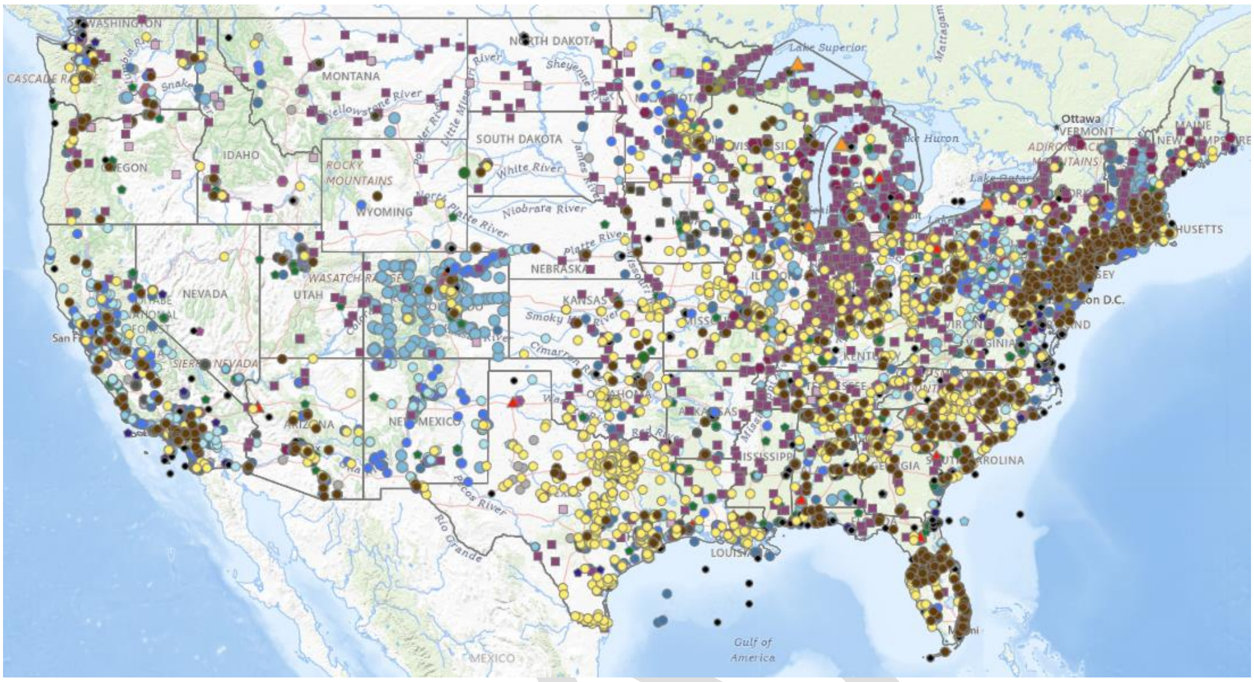

**Figure 7. The latest update of an interactive map of mainland USA showing PFAS monitoring provided by US EPA via the PFAS Analytics Tool (graphics generated via the PFAS Analytics Tool provided by US EPA)[26].**

It should be noted that many States of the U.S. have their own legislation and acts upon PFASs.

Canada

In Canada most uses for PFOS were prohibited in 2016 aside from exemptions for specific uses. In 2012, the Federal Government concluded that PFOA was of ecological concern. Nevertheless, Health Canada maintains the point of view that PFOS and PFOA are not of concern for human health at current levels of exposure. In June 2019, Transport Canada allowed airports to use PFAS-free firefighting foam, which shows a more precautionary approach as it targets the whole class of PFASs.

In 2018, the Canadian Federal-Provincial-Territorial Committee on Drinking Water and the Federal-Provincial-Territorial Committee on Health and the Environment released a technical guideline document, which reviewed and assessed all identified health risks associated with PFOS and PFOA in drinking water. It incorporated available studies and approaches and took into consideration the availability of appropriate treatment technology. Based on the review, the drinking water guideline for PFOS and PFOA was set at a maximum acceptable concentration (MAC) of 0.6 µg/L (600 ppt) and 0.2 µg/L (200 ppt) based on the general population.

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[26] https://awsedap.epa.gov/public/extensions/PFAS_Tools/PFAS_Tools.html, date of access: 2025-05-15.

New Zealand and Australia

The PFAS National Environmental Management Plan (NEMP), January 2020, from the National Chemicals Working Group of the heads of EPAs Australia and NZ, provides nationally agreed guidance on the management of PFAS contamination in the environment, including prevention of spreading of contamination. It supports collaborative action on PFASs by the Commonwealth, state and territory and local governments around Australia. The NEMP is an appendix to the Intergovernmental Agreement on a National Framework Responding to PFAS Contamination. The NEMP reflects the current state of knowledge and is updated regularly to reflect new scientific evidence and guidance. The NEMP recognises the need for sound regulation of PFASs by each jurisdiction in a way that can adapt to local circumstances and emerging priorities.

Australia will continue to participate in the Stockholm Convention's processes and to address any domestic implementation requirements that may result if PFHxS or other PFASs are listed. In the meantime, the globally accepted standards outlined in the convention for the use and management of persistent organic pollutants are a fundamental point of reference for the guidance provided in the NEMP.

Ratification of the PFOS and PFOA listings or future listings of PFHxS or other PFASs in the Stockholm Convention would mean Australia accepting and implementing international standards for the management of these chemicals. For example, this would include requirements regarding waste that contains listed chemicals, including related substances as defined by the listing, at a level above the content limit of 50 mg/kg.

## 2.2.2. **Discussion of possible regulatory measures**

### 2.2.2.1. REACH restriction

A restriction on manufacturing, marketing and use of PFASs, and articles containing PFASs is assessed to be the most appropriate way to limit the risks for human health and the environment. In particular, the import of articles containing PFASs can be controlled this way. The information on occurrence of PFASs in articles is limited.

In line with risk management of other substances of the PFASs group the Dossier Submitters suggest a restriction as the most appropriate measure to minimise concentrations in the environment. The advantages of a restriction are:

- The possibility to address a group of substances, including all potential precursors.
- The possibility to cover imported articles, which in this case is a considerable source of PFAS emissions into the environment.

The regrettable substitution seen in the case of long-chain PFASs and the very high number of PFASs on the market show that the approach taken until now of regulating them individually (or in small groups of closely related substances) is not efficient and does not fully address the concerns they pose. Widespread use of multiple substances from the PFASs group increases the risk of combined effects from PFASs. This leads to the conclusion that it would be beneficial if a future regulatory initiative concerning PFASs addresses them as a group (see section 1.1.2 on Justification for grouping).

Recent publications have investigated various approaches that could be taken to regulate PFASs as a chemical class or as sub-groups, based on their intrinsic properties (e.g. persistence, bioaccumulation, long-range transport potential, toxicity, mobility and molecular size). The authors conclude that an approach to grouping based on persistence alone could be justified considering that the continuous release of persistent chemicals will lead to widespread, long-lasting, irreversible and increasing contamination. It will also result in increasing probabilities of adverse effects on human health and the environment.

Because of the many sources of PFASs in the environment and considering their high persistence, in addition to limiting the emissions at the source, there is a need to identify and reduce existing pollution in the different environmental compartments as much as possible. Restricting PFAS uses under the chemicals and product specific legislations could therefore be complemented with actions under other legislative frameworks (water, food, industrial emissions and waste) and non-legislative initiatives (soil).

A restriction under the chemicals legislation (REACH) is considered the most effective tool to manage the risk from substances, such as PFASs that are used in industrial processes but also in products. A restriction can include the ban of the manufacture, placing on the market or use of a chemical substance, or a group of substances. Additionally, it can use other requirements to address risks (such as use of RMM). It applies also to imported products and it is flexible, because it can include derogations, unlimited in time or time limited. Therefore, the most appropriate EU-wide instrument to address PFAS concerns at the source is a REACH restriction.

#### 2.2.2.2. SVHC identification

Eleven different PFASs have been listed on the Candidate List (see section 2.2.1.2). In some cases it is specified that the listing includes salts and isomers. The substances are identified as SVHC (published in accordance with Article 59(10) of the REACH Regulation), based on PBT/vPvB, as ELoC or toxic for reproduction properties. An inclusion of PFASs in general in the Candidate List would, however, clearly establish that the substances have properties that warrant consideration as substances of very high concern based on REACH Article 57 criteria. Intrinsic properties of PFASs as a group of substances can also be discussed in detail in an Annex XV restriction dossier which is not limited to define criteria for the concern of SVHC. In addition, the outcome and benefit of a restriction dossier regarding emission reduction would be clear and direct and would be a less time-consuming process compared to a sequence with SVHC identifications followed by restriction. SVHC identification for PFASs as a group would not be an effective regulatory risk management option as individual dossiers would need to be prepared for every single substance. This would, in many cases, require the creation of new studies to prove the fulfilment of the SVHC criteria according to Article 57 of the REACH Regulation. Additionally, SVHC identification does not prohibit the use of these substances but imposes notification and information obligations (Article 7 and Article 33 of REACH) on certain actors in the supply chain if the substances are present in articles. While it is acknowledged that SVHC identification does to some extent increase the pressure for substitution, it is neither an effective nor practical regulatory risk management option in the view of the Dossier Submitters as it would not lead to a minimisation of PFAS emissions.

#### 2.2.2.3. Authorisation

According to Article 58(3) of the REACH regulation, priority for inclusion of SVHC in Annex XIV shall normally be given to substances with (a) PBT or vPvB properties, or (b) wide dispersive use, or (c) high volumes. Only substances that were previously added to the Candidate List can subsequently be included into Annex XIV following prioritisation and become subject to authorisation. No PFASs are listed on the Authorisation List (Annex XIV) so far.

As explained above, the SVHC identification of all PFASs fitting the chemical definition would be very difficult. Authorisation addresses the use of a substance as such, including the incorporation into articles, and in mixtures above 0.1%. Since the aim is to minimise the exposure of the environment and humans to PFASs, these substances need to be substituted where technically and economically feasible including in imported articles and uses in concentration below 0.1%. An inclusion in Annex XIV and authorisation would, however, not address PFASs in imported articles or uses in concentration below 0.1%. However, both aspects could be addressed in a restriction.

An advantage of authorisation is that the burden of proof is on the user of the substance. For each application, the user should demonstrate that the socio-economic benefits outweigh the risk and that there are no adequate alternatives. A disadvantage is that with an authorisation it cannot be prevented that a substance similar to a substance on the Authorisation List with comparable negative properties for human health and the environment is used if it has not yet been included in the authorisation procedure itself. Therefore, one PFAS could be replaced by another PFAS, i.e. regrettable substitution.

Furthermore, relying on the authorisation procedure for PFASs with numerous applications, it can be expected that there will be an extensive number of authorisation requests which all need to be evaluated by RAC and SEAC. This would mean an unrealistic overall workload. This would not only happen once (as for restriction), but repeatedly as authorisation is granted for a limited period. The knowledge base for writing applications for authorisations would thus have to be created in a myriad of companies all over Europe, which would be cost- and time-intensive. Thus, authorisation is concluded to be neither an effective nor practical regulatory risk management option by the Dossier Submitters.

### 2.2.2.4. Harmonised classification and labelling (CLH) and/or self-classification

The main concern for all PFASs in scope of this restriction proposal is their persistence, which is not among the classification criteria under CLP. Even though PBT/vPvB and PMT/vPvM properties have recently been added to the CLP Regulation as new hazard classes, harmonised classification as being persistent, only, is not foreseen. CLH is therefore concluded only to be an appropriate regulatory risk management option for (groups of) selected PFASs with additional dangerous properties that justify the classification. However, data on harmful properties is lacking or insufficient for many of the members of the PFASs family, and for these CLH is not an applicable option. Additionally, harmonised classification and labelling does not necessarily raise the hurdle to use the substances for article/product manufacturing. Thus, emissions would continue unhindered.

### 2.2.2.5. Other regulations outside REACH and CLP

An overview of regulations next to REACH that could provide risk mitigation, is given in Table 7. However, these regulations could not prevent the manufacture, placing on the market and use of PFASs. In the view of the Dossier Submitters, it is necessary to restrict the manufacture and use of PFASs as much as possible to prevent continued environmental pollution by these very persistent substances. REACH thus offers the broadest measure to mitigate future emissions. In comparison to the regulations listed below, it offers a unified approach tackling the problem already at the beginning of the process ("manufacturing"), while other regulations can only solve a distinct part of the problem. Therefore, the regulations below are not considered as efficient and practical.

**Table 7. EU Legislations other than REACH.**

| Relevant EU-legislation other than REACH | Community-wide option for risk management |
|---|---|
| Water Framework Directive,<br>Directive 2000/60/EC | Releases of PFASs occur to the surface water and ground water. The aquatic compartment is an important media for PFASs in the environment and WWTPs are a main source of emissions into that compartment. Therefore, it is proposed to include PFASs as priority hazardous substances including setting an EQS (Directive on Environmental Quality Standards (EQS) (Directive 2008/105/EC amended by 2013/39/EC)) and considering the Groundwater Directive (2006/118/EEC).<br>However, WWTPs are not the only emission source and the aqueous media is not the only environmental media of concern and therefore the use of the directive alone is insufficient. It would be more efficient to minimize emissions of PFASs directly at their source. |
| EU Soil health law | The European Commission has announced it will propose a Soil Health Law in 2023.<br>The aim of the Soil Health Law proposal announced in the EU soil strategy for 2030 is to specify the conditions for a healthy soil, determine options for monitoring soil and, lay out rules conducive to sustainable soil use and restoration. Even if PFASs were addressed in this legislation, this would not address the source of the emissions and hence, not help to minimise emissions into the environment in the first place. |

| **Relevant EU-legislation other than REACH** | **Community-wide option for risk management** |
|---|---|
| Sewage Sludge Directive,<br>Directive 86/278/EEC | So far, PFASs are not addressed in the Sewage Sludge Directive. But limit values for PFASs in sludge could be established during a revision of this Directive.<br>However, only levels in sludge would be regulated, not manufacture, use and emissions that ultimately result in contamination of sludge.<br>Therefore, regulation of PFAS by the Sewage Sludge Directive is not considered an effective means for minimizing PFAS emissions. |
| Waste legislation (e.g. recollection, or classification as hazardous waste | Waste management requirements currently only address PFASs and PFAS-containing mixtures if they are classified and labelled as hazardous. Changes to the waste legislation would be needed to cover PFASs in general and also PFAS containing articles.<br>Nevertheless, such requirements can only be considered as complementary to the proposed restriction to manage risks related to derogations. In addition, waste management requirements can be applied to control emissions from articles already in use (i.e. in the 'technical stock'). However, waste legislation alone is not an effective means for minimizing PFAS emissions from other stages of the life cycle. |
| Directive on industrial emissions (integrated pollution prevention and control),<br>Directive 2010/75/EU | This Directive addresses pollution from large industrial installations, which can be considered as complementary to a restriction to manage risks related to derogations and risks related to articles already in use.<br>On 5 April 2022, the Commission adopted proposals for revised EU measures to address pollution from large industrial installations, in line with EU Green Deal. |
| Volatile Organic Compounds (VOC) Directive,<br>Directive 1999/13/EC | The VOC Directive addresses pollution of the environment arising from emissions of volatile organic compounds, VOC (i.e. organic solvents), due to the use of organic solvents in certain activities and installations. A concern related to the use of VOCs is the evaporation of the solvents and contribution of VOCs to formation of ozone in the troposphere (i.e. ground level). Previously, VOC emissions were regulated in the VOC Directive (Directive 1999/13/EC), while today the Paints Directive (Directive 2004/42/CE) aims to limit the total content of VOC in certain paints and varnishes and vehicle refinishing products. As fluorinated gases have only a low potency for ground-level ozone formation, see Annex B.7.9, it is considered not the most appropriate approach to address them as VOCs in regulations targeting ground-level ozone formation. |
| EU legislation Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food<br><br>EU legislation Commission regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food | According to Article 5 of this regulation, specific measures for certain groups of materials or articles can be established. In the course of that, the use of PFASs in or their migration from food contact materials (e.g. paper, rubber, coatings) could be regulated (i.e. only be allowed below a certain limit value).<br><br>Only substances listed in Annex I of this regulation are allowed to be used as monomers or additives for plastic food contact materials.<br>In Annex I of this regulation already contains concentration limits for PFOA, which result in minimal or no release into food. Annex I could be expanded to cover also other PFASs used on plastic food contact materials. However, this only addresses the presence of PFAS in such articles. It does not set any measures for the production process of the articles nor does it take into account releases into the environment from these articles (e.g. when they become waste). |
| EU legislation under consideration | The PPWR is still under discussion, but a compromise text has been agreed between Parliament and Council on March 15, 2024[27]. |

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[27] https://data.consilium.europa.eu/doc/document/ST-7859-2024-INIT/en/pdf, date of access: 2024-04-05.

| Relevant EU-legislation other than REACH | Community-wide option for risk management |
|---|---|
| Revision of Packing and Packaging Waste regulation:<br>Packing and Packaging Waste (amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC). | If implemented, the PPWR will have an effect on the baseline for food packaging containing PFAS, as PFASs in food packaging will be banned under this regulation (see preambles 15a and 15b and article 5(2)(a)). The text of the ban uses the same definition of PFAS (including the derogated molecular structures) and associated concentration limits proposed by the five Member States for the 'universal' PFAS restriction. The ban has an 18-month transitional period.<br>As the opinion-making and decision-making process is still ongoing, it is not taken into account in the legislative baseline for the Universal PFAS restriction. |

### 2.2.3. Active substances in Plant Protection Products (PPP), Biocidal Products (BP) and Medicinal Products (MP)

**General regulatory aspects**

In the EU, active substances in plant protection products (PPP), biocidal products (BP) and human and veterinary medicinal products (MP) are regulated by an approval system under their respective regulations (see Table 8). In contrast to (industrial) chemicals, active substances may not be marketed in the EU Member States unless a product authorization has been granted.

The specific regulatory status of active substances in PPP, BP and human and veterinary MP makes certain provisions of the REACH regulation applicable to these substances. According to REACH Article 2(5)a, substances in MP for human or veterinary use within the scope of the relevant EU legislations are exempted from certain REACH requirements like registration, evaluation and authorisation. Active substances that are manufactured or imported for use in PPP or BP and evaluated under their respective EU regulations are considered to be registered under REACH according to Article 15. Further, according to REACH Article 56(4), the authorisation requirement for substances included in REACH Annex XIV does not apply to the use in PPP and BP. However, active substances in PPP, BP and MP may still be subject to REACH restrictions, if they are not explicitly derogated.

The REACH Regulation and the BPR, PPPR as well as the respective Regulations addressing MP apply in a cumulative manner. This means that a complete ban of PFAS in a restriction under REACH would also apply to the use of the substances in such products. A general ban of PFAS under REACH would not distinguish between PFAS active substances or co-formulants/excipients or as constituents of co-formulants/excipients in these products (PPP, BP or MP). Nor could the sector specific regulations introduce an exemption from an existing REACH restriction.

**Table 8. Active ingredients in PPP, BP and MP and their respective legislation.**

| Uses | Legislation |
|---|---|
| Active substances in plant protection products | Regulation (EC) No 1107/2009 (PPPR) |
| Active substances in biocidal products | Regulation (EU) No 528/2012 (BPR) |
| Active pharmaceutical ingredients (API) in human medicinal products | Directive 2001/83/EC (human)<br>Regulation (EC) 726/2004 (human and veterinary) |

| Uses | Legislation |
|---|---|
| Active pharmaceutical ingredients (API) in veterinary medicinal products | Regulation (EC) 726/2004 (human and veterinary)<br>Regulation (EC) 2019/6 (veterinary) |

**PFAS uses**

Active substances that fulfil the PFAS definition are commonly characterized by the presence of one or more $CF_3$-group(s) in their molecular structure. The common use of $CF_3$-groups in active substances is due to a combination of the stability of the C-F bond and the electron withdrawing effect of the $CF_3$-group. Based on these fundamental features, the introduction of a $CF_3$-group in the molecular structure of biologically active substances is utilized to modulate and optimize specific properties, such as potency, stability, lipophilicity, permeability etc. (Johnson et al., 2020).

For non-exhaustive lists of PFAS active substances in PPP, BP and MP see Appendix A.3.25. in Annex A.

According to numerous comments received in the consultation on the Annex XV report in 2023, PFAS substances are also used in the production of active substances.

Several comments include information regarding the use of PFAS starting materials and PFAS intermediates (e.g. comment IDs #3924, 3991, 4041, 4207, 4222, 4223, 4438, 4455, 4588, 4490, 5384, 5390, 5578, 5962, 5969, 6059, 6232, 6285, 6354, 6436, 6758, 7248, 7554, 7596, 7756, 7778, 7784, 7875, 7916, 8133, 8145, 8152, 8160, 8163, 8165, 8168, 8176, 8189, 8191, 8197, 8201, 8207, 8262, 8264, 8283, 8288, 8314, 8379, 8393, 8396, 8531, 8540, 8623, 8675, 8683, 8690, 8719, 8725, 8765, 8817, 8870, 9063, 9072, 9117, 9153, 9168, 9215, 9274, 9276, 9304, 9322, 9327, 9332, 9361, 9390, 9444, 9551, 9590). For the manufacturing of PFAS active substances, the starting materials as well as some of the intermediates (isolated or non-isolated) along the synthesis pathway are usually also PFASs. The replacement of these starting materials or intermediates is not possible as the PFAS moiety must be introduced into the molecule in the manufacturing process. In rare cases, intermediates that fulfil the PFAS-definition are also used for the manufacturing of non-PFAS active substances. For example, trifluoromethanesulfonates (triflates) are transient intermediates in the synthesis of non-PFAS active substances. The highly electron withdrawing nature of these type of PFAS groups effectively activates the molecule for further reactions. The use of non-PFAS activating groups or the use of other synthetic pathways could theoretically be possible. However, this would be a case-by-case assessment. If alternative process chemicals and/or synthesis routes would be available, this would require the development of new chemistry processes including necessary regulatory approvals with the corresponding timelines involved.

Several comments include information regarding the use of process chemicals that meet the PFAS-definition (e.g. comment IDs #3991, 4041, 4207, 4222, 4438, 4455, 4490, 4588, 5384, 5390, 5578, 5962, 6232, 6436, 6758, 7248, 7554, 7596, 7756, 7778, 7784, 7875, 7916, 8133, 8145, 8152, 8160, 8163, 8165, 8168, 8176, 8189, 8191, 8197, 8201, 8207, 8262, 8264, 8283, 8284, 8288, 8314, 8379, 8393, 8396, 8531, 8540, 8623, 8675, 8683, 8690, 8719, 8725, 8765, 8817, 8870, 8987, 9053, 9063, 9072, 9117, 9153, 9168, 9215, 9274, 9276, 9304, 9322, 9327, 9332, 9361, 9390, 9444, 9551, 9590). In the context of this restriction, process chemicals refer to substances other than starting materials or intermediates, used in the manufacturing of an active substance. Process chemicals that meet the PFAS-definition can be used in the production of PFAS active substances, as well as non-PFAS active substances, as their structure does not become part of the active substance molecule. PFAS process chemicals are used for various functions in the production process such as reagents, catalysts, activating agents, auxiliaries, ligands, and solvents. Common applications of PFAS process chemicals are e.g. trifluoracetic acid (TFA) as a catalyst in solid phase peptide synthesis, trifluoromethanesulfonic anhydride (triflic anhydride) as activating agent in substitution reactions, and benzotrifluorid as solvent in halogenation reactions. PFAS process chemicals have been selected for optimum performance in specific synthetic steps in the manufacturing process but could theoretically be substituted for non-PFAS chemicals in some cases. Alternatively, other synthetic routes not requiring PFAS chemicals could be developed. However, this would be a case-by-case assessment. If alternative process chemicals and/or synthesis routes would be available, this would still require the development of new chemistry processes including necessary regulatory approvals.

In the following paragraphs, specific considerations for actives substances within the different legislations are described.

### Specific considerations for active substances in PPP and BP - Regulation (EC) No 1107/2009 (Plant Protection Product Regulation, PPPR) and Regulation (EU) No 528/2012 (Biocidal Product Regulation, BPR)

PPP are designed to protect plants and crops against weeds, diseases and pests and are usually applied directly on outdoor crops and therefore direct emission to the environment takes place. BP control fungi, pests or organisms (e.g. bacteria, viruses, parasites), which are harmful to the health of humans, animals or the environment, or damage materials. BP have various applications which do not necessarily have direct emission to the environment. According to the requirements of the PPP and the BP regulation, in a first step active substances (AS) to be used in the respective products need to be approved. During this approval process AS are assessed for their hazardous properties for both, human health and the environment. The Regulations define certain exclusion criteria, i.e. if a substance has certain hazardous properties such as for example PBT or vPvB properties it cannot be approved as an AS. Substances meeting 2 of the three PBT criteria can only be approved as so called candidates for substitution (CfS). CfS are only approved for 7 years (instead of 10 years). It needs to be noted though that, persistence (P) as such is not an exclusion criterion. However, since PPPs and BPs are designed to be toxic, the many AS are classified as T, so that in the case of persistent PFAS they would become CfS. Another important aspect is that AS can only be approved if it can be demonstrated in a risk assessment that the risk associated with their use in PPP/BP is acceptable. This includes an extensive environmental risk assessment taking into account also degradation products. In addition, also the efficacy of an AS needs to be demonstrated in a representative use of a PPP/BP.

After an AS has been approved for the use in PPP/BP, products containing the AS need to be authorised before they can be placed on the market. In this authorisation procedure, the applicant needs to demonstrate that the products do not cause any harm to human health or the environment.

In case the PPP/BP contains a CfS, a comparative assessment needs to be performed by the authorising authority. In this comparative assessment, national authorities first will check the consequences of an authorisation of the PPP/BP compared with available alternatives. Factors to be considered are consequences for minor uses, risk of developing resistance, the effectiveness of the alternatives and practical and economic consequences. This assessment of whether available alternatives are sufficient for the respective purpose then governs the outcome, i.e. whether the product can be authorised or not. Such an investigation would among other aspects consider, if there are possible effective alternatives, how they are used in strategies against resistance development, etc.

A general restriction of PFASs in PPP would entail that at least 48 active substances in over 200 products cannot be used anymore. For BP, nine active substances would be covered by a broad PFAS restriction, five of these being candidates for substitution and their use has been considered as necessary according to the comparative assessment performed. Limiting the number of AS available would have consequences in terms of availability of e.g. fungicides, insecticides, rodenticides and herbicides used in a variety of crops and organisms. Limiting the number of different PPPs/BPs generally aggravates resistance management.

TFA formation from active substances and release to the environment of TFA, is currently under increasing concern. EFSA requests, under Art 31 - Scientific and technical assistance, a review of the toxicological reference values for trifluoroacetic acid (TFA)[28]. The risk assessment deadline is scheduled for 28-02-2026.

**Specific considerations for active substances in human and veterinary MP - Directive 2001/83/EC (human MP), Regulation (EC) 726/2004 (human and veterinary MP), and Regulation (EC) 2019/6 (veterinary MP)**

A medicinal product consists of one or more active substances (active pharmaceutical ingredients, APIs), other supplementary ingredients (excipients) and an immediate packaging. Medicinal products are considered important for the protection of the health of humans. Human MP are important for the protection of humans from diseases. Residues of medicines are released via sewage in the environment.

Veterinary MP are important for the protection of animals and, indirectly, humans from diseases. Also, veterinary MP are important for the welfare of animals and the supply of food. The excretion of urine and feces from medicated animals and the application of contaminated manure to agricultural soils are important pathways for veterinary MP to enter the environment.

In the EU, human and veterinary MP are regulated by an authorisation system under their respective regulations. For all medicinal products a Marketing Authorisation (MA) is required in order to be put on the market in the EU/EEA.

Human MP are regulated in the EU by their sector-specific legislations and expert bodies/authorities in accordance with Regulation (EC) 726/2004 and detailed in Article 8(3) of Directive 2001/83/EC. In the case of a market authorization application (MAA) for a MP intended for human use, it is since 2006 mandatory to include an environmental risk assessment (ERA) of the API. This assessment is necessary for new MP to be placed on the market or where there is potential for significant increase in environmental concentrations as a result of modifications to existing marketing authorizations. The ERA includes a hazard assessment part and a risk assessment part. Other components of the MP, such as excipients, are not part of the ERA. The ERA is based on the use of the product, the physico-chemical, ecotoxicological, and fate properties of the API and the primary aim of the ERA is to protect aquatic and terrestrial ecosystems, including surface water, groundwater, soil, species at risk of secondary poisoning and the risk for the microbial processes in sewage treatment plants (STPs). In the hazard assessment, a PBT/vPvB assessment of the API according to REACH guidelines is included. When the possibility of environmental risks cannot be excluded, specific arrangements to limit the environmental impact shall be made. The applicant should propose and discuss a strategy for risk mitigation. Appropriate mitigation measures should generally

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[28] https://open.efsa.europa.eu/questions/EFSA-Q-2024-00502 and https://www.efsa.europa.eu/en/topics/per-and-polyfluoroalkyl-substances-pfas, for both, date of access: 2025-06-03.

aim at minimising the quantity discharged into the environment by precautionary/safety measures.

Although possible negative effects of APIs used in human MP on the environment are assessed in the ERA and risk mitigation measures can be deemed necessary within the current legislation, the ERA does not have a decisive effect on the authorization process. However, the authorization process is under revision. On April 26, 2023, the Commission adopted a proposal for a new Directive 2001/83/EC and a new Regulation (EC) 726/2004, which revise and replace the existing general pharmaceutical legislation. As part of this revision, the Commission proposes to strengthen the ERA requirements by e.g.:

- Refusal of a Marketing Authorisation based on environment concerns, such as lack of adequate evidence that environmental risks were evaluated and risk mitigation measures were taken,
- Prioritisation of ERA for legacy APIs, which were placed on the market before 2006,
- Increased interlinkage across non-pharma legislations.

A few publications have been taken into account to strengthen ERA requirements in this revision of the EU medicines legislation (Gildemeister et al., 2023; Moermond et al., 2023). The finalized version of the revised Directive 2001/83/EC and Regulation(EC) 726/2004 is not publicly available yet, is expected soon to be available.

Veterinary MP are regulated by their sector-specific legislation and corresponding expert bodies/authorities in accordance with Regulation (EU) 2019/6 on veterinary MP. A market authorization application (MAA) for a veterinary MP shall, similarly to human MP, contain an environmental risk assessment (ERA) of its API. As for human MP, the environmental risk assessment (ERA) shall contain an assessment of the environmental risks for APIs for terrestrial and aquatic ecosystems as well as a PBT/vPvB assessment according to REACH guidelines.

An overview how much TFA theoretically can be formed per PFAS API (kg) has been recently indicated[29]. This is performed on a national level, hence it is not an EU overview. Since medicinal product use differs quite significantly per MS, this is an indication, how much TFA is formed from APIs (in NL).

Finding alternatives for PFAS actives substances is done for APIs by medical professionals, for example at anaesthetics. General anaesthesia is administered to more than 300 million surgical patients worldwide, every year. It is maintained either through total intravenous anaesthesia (TIVA), by infusion of propofol, or through inhalational anaesthesia (IA), by inhalation of the volatile anaesthetics desflurane, isoflurane or sevoflurane. A systematic review and meta-analysis found that postoperative mortality and organ-related morbidity was similar between patients receiving total intravenous anaesthesia versus inhalational anaesthesia. Total intravenous anaesthesia offered advantages in postoperative recovery. The overall results suggest that TIVA and IA are both safe and efficacious. This means that secondary considerations may be taken into account, including the environmental impact of volatile anaesthetics (Kampman et al., 2024). Recently it has been acknowledged that the

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[29] https://www.vzinfo.nl/genees-en-hulpmiddelen-en-lichaamsmaterialen/gevolgen, date of access: 2025-06-03.

aqua toxic effects of volatile anaesthetics potentially pose a (much) greater concern than those of propofol, especially in the long term. This adds to the environmental arguments that there is a need to adopt more sustainable anaesthetic practices, prioritizing alternatives like TIVA for maintenance anaesthesia to address the ecological and health hazards presented by PFAS volatile anaesthetics (Kalmar et al., 2024).

In addition to the PFAS uses related to APIs in MP that are covered in this section, further applications of PFASs associated with the market authorization of medicinal products have been identified based on information provided by stakeholders during the consultation on the Annex XV report. These PFAS uses are assessed elsewhere in the dossier:

- PFASs used as excipients (substances (pharmaceutical grade) other than the active substances used, usually to formulate the MP). These PFAS uses are addressed in the use sector ‘Other medical applications’ (see Annex A.3.20).
- Fluoropolymers used in immediate packaging (also referred to as primary packaging). These PFAS uses are addressed in the use sector ‘Other medical applications’ (see Annex A.3.20).
- Fluoropolymers used in drug delivery devices (drug-device combination products are medicinal products approved for use co-packed with specific drug delivery devices). These PFAS uses are addressed in the use sector ‘Other medical applications’ (see Annex A.3.20).
- Fluoropolymers used in components in equipment for manufacturing and analysis/quality control of medicinal products (e.g. gaskets, seals, O-rings, fittings, piping, valves, filters, filtration membranes etc.). These PFAS uses are addressed in the use sectors ‘Sealing applications’ (see Annex A.3.18), ’Broader Industrial Uses’ (see Annex A.3.24), and ‘Technical textiles’ (see Annex A.3.23).
- PFAS chemicals used in analytical methods for quality control purposes. These PFAS uses fall under the SR&D exemption according to REACH Article 67.

**Conclusions regarding active substances in PPP, BP and MP**

As according to the requirements of the PPPR/BPR extensive environmental risk assessments are carried out in relation to the use of the active substances and also aspects other than risk-based considerations play a role during approval of active substances and authorisation of PPP/BP (e.g. efficacy, resistance management), the Dossier Submitters propose to exclude active substances used in PPP/BP from a general restriction under REACH. This derogation should, however, not apply to other substances in PPP/BP (such as co-formulants) as these are not assessed in such detail.

Since PFAS starting materials, intermediates and process chemicals are required in the approved manufacturing processes of the active substances in PPP, BP and MP, the Dossier Submitters consider that the abovementioned substances should be covered by the proposed derogation of the active substances in PPP, BP and MP.

Within medical professionals, a push away from PFAS active substances is already taking place, for example at anaesthesia, by successfully replacing inhalational (F-gases) by intravenous anaesthesia. Patient safety was taken into account during this transition and it seemed that both the PFAS alternative and inhalational anaesthesia version are safe and efficacious.

There is increasing concern of the major degradation product of active substances, TFA. EFSA (PPP) requests a review of toxicological reference values for TFA, a call for data was distributed. Outcome is to be expected spring 2026.

The environmental risk assessment of actives substances in MP is similar to the PPP and BP assessment, although not as extensive and without a decisive effect on the authorization process. The general pharmaceutical legislation is currently under review, and it is foreseen that the environmental risk assessment (ERA) of actives substances in MP will be strengthened. The outcome will be published shortly. As the environmental risk of active substances is assessed along with crucial aspects such as clinical efficacy and safety for patients during the the authorisation of an MP, the Dossier Submitters propose to exclude active substances used in MP from a general restriction under REACH. This time-unlimited derogation should, however, not apply to other substances in MP (such as excipients) as these are not assessed in such detail.

It needs to be acknowledged that the use of PFASs as active substances in PPP, BP and MP leads to (in case of PPP and BP partly intentional) environmental emissions. A rough estimate indicates that PPP account for 2% of total EU sales of substances that fulfil the PFAS definition (0.2% of API used in MP; no data available for BP), see Annex A.3.25. Therefore, taking into account the risks associated with PFASs in the scope of this restriction proposal the Dossier Submitters recommend that measures to minimise emissions from the use of PFAS as active substances in PPP, BP and MP are taken in the context of the respective sector-specific regulations.

To support the European Commission in taking action, the proposed derogation is combined with reporting requirements for the placing on the market of PFAS active substances in PPP, BP and human and veterinary MO. It is proposed that manufacturers and importers of active substances provide information on which PFASs are used as well as the respective tonnage to the European Chemicals Agency (ECHA) on an annual basis. The annual reports will help to get an understanding of the magnitude of continuing emissions as well as the progress made in relation to substitution and/or minimization of releases.

### 2.2.4. Conclusion on the most appropriate regulatory risk management options

A restriction is considered the most effective and efficient way to manage such a large and complex group of substances that are used in numerous applications. In addition, a restriction can cover imported articles. A broad restriction is therefore preferable to authorisation.

A broad restriction under REACH covering all PFASs as a group would:

- limit as many uses as practically possible and thereby minimise emissions and human and environmental exposures to PFASs;
- include currently unknown PFASs and PFAS uses;
- prevent regrettable substitution of restricted PFASs with other PFASs with similar concerns.

However, it is proposed that PFASs used as active substance (but not as co-formulants) in PPP, BP and human and veterinary MP should be generally derogated from this REACH restriction (see section 2.2.3) as they are addressed under their respective regulations. This derogation is, however, linked to a reporting requirement.

Similar generic derogations for other sectors are not proposed as either sector-specific legislation is not applicable to PFAS or, if in principle applicable to PFAS, does not take into account environmental risks arising from the use of the substances to the extent this is considered under REACH or under the PPPR, the BPR and potentially in future under the MPR. The latter is for example the case for the Cosmetics Regulation, Food Contact Materials Regulation and the Medical Devices Regulation.

## 2.3. Restriction scenario(s)

### 2.3.1. Main restriction options assessed

Based on the conclusions of the risk assessment, the releases of PFASs are considered to pose a risk to the environment that is not adequately controlled. In response to the identification of this risk, diverse risk management options (RMOs) were analysed to identify the most appropriate measure to address the risk. In Section 2.2.4, it is concluded that a REACH restriction is the preferred risk management option. The proposed restriction should avoid releases of PFASs to the environment as much as possible. Since PFASs are chemically very stable, it is important to consider releases during all stages of the life cycle, including the waste stage. The best option to avoid PFAS emissions to the environment during manufacture, the production and use of PFAS-containing articles and at the waste stage is to prohibit the manufacture and use of PFASs to the largest extent possible.

As a starting point, the proportionality of a full ban (i.e. Restriction Option 1, henceforth referred to as RO1) of all PFASs is therefore analysed. RO1 is suggested to enter into force after a transition period of 18 months. A transition period of this length is generally considered reasonable for selling existing stocks of PFASs and PFAS-containing materials in the supply chain. This most stringent restriction option is then compared to a Restriction Option 2 (RO2), being a ban of all PFASs after a transition period of 18 months except for, in most cases, time-limited use-specific derogations, of either a duration of five or 12 years after the end of the transition period. The appropriate length of a derogation period in the context of a restriction ideally emerges from a socio-economic analysis that quantitatively assesses the costs and benefits associated with several restriction options that solely differ with respect to the length of the derogation period. Where such restriction options can be assessed quantitatively, the resulting cost-benefit ratios would allow for the identification of the derogation period that optimises the net benefits to society. Due to the significant differences with respect to, for example, the existence of alternatives across uses (and consequently costs), such an assessment would ideally have to be conducted at use level in the case of the restriction of PFASs. While maximising the net benefits of the restriction, such an approach would likely also lead to a wide variety of derogation periods for different uses. Given the big scope of the restriction, a streamlined approach with default transition periods was deemed more praticable from an enforcement perspective. The Dossier Submitters consider the time periods of five and 12 years normally sufficient for industry to take benefit from technical progress and to carry out scientific R&D activities to find and deploy technically and economically feasible alternatives (which ultimately limits the costs of a restriction to society).

The duration of the transition period and derogations that are considered are summarised in Table 9. Derogations are proposed on the basis of the criteria described in the text following the table. These qualitative criteria have been employed with a view of ensuring a consistent approach of regulation that is not impaired by differences in the extent of quantification of the costs and benefits that was possible for different uses.

**Table 9. Restriction options (ROs) assessed.**

| **Restriction option (RO)** | **Transition period before RO takes effect** | **Duration of derogation** |
|---|---|---|
| **RO1: Full ban** | 18 months | Not applicable |
| **RO2: Ban with use-specific derogations** | | 5 years after transition period ends |
| | | 12 years after transition period ends |
| | | Time-unlimited (only for specific uses) |

A five-year derogation is proposed when sufficiently strong evidence is available that

(i) points to the non-existence of technically and economically feasible alternatives on the market at the entry-into-force (EiF) date but where possible alternatives to the PFAS use have already been identified that are however still in the development phase, or
(ii) known alternatives are not available in sufficient quantities on the market at the EiF date or known alternatives cannot be implemented before the transition period ends.

A 12-year derogation is proposed when sufficiently strong evidence is available that:

(i) points to the non-existence of technically and economically feasible alternatives on the market at the EiF date, e.g. Research and Development (R&D) efforts did not identify possible PFAS-free alternatives so that it is likely that they will not become available in the near future, or
(ii) certification or regulatory approval of PFAS-free alternatives cannot be achieved within a five-year derogation period.

For some specific uses there may be reasons of practical nature on the basis of which time-unlimited derogations could be necessary. The Dossier Submitters consider such time-unlimited derogations justified for e.g. (i) use of PFASs in refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives (see section 2.4.1.1), (ii) refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months after EiF and (iii) toners and latex printing inks for use in existing equipment put on the market until 13.5 years after EiF.

As indicated in the criteria above, a derogation requires a sufficiently strong evidence base to justify its necessity. Consequently, in cases where the available evidence base is considered weak, a derogation is not supported.

The environmental and socio-economic impacts of the considered restriction options are assessed separately for manufacturing of PFASs, TULAC, food contact materials and packaging, metal plating and manufacture of metal products, consumer mixtures, cosmetics, ski wax, applications of fluorinated gases, medical devices, transport, electronics and semiconductors, the energy sector, construction products, lubricants, petroleum and mining, printing applications (including consumables, such as toners, and permanent parts), sealing applications, machinery applications, other medical applications, military applications, explosives, technical textiles and broader industrial uses.

For RO1, environmental impacts are assessed quantitatively, based on available emission data, and information on the expected market growth. The applied growth rates are described in section 1.3.2. When assessing the environmental impacts for RO2, the assessment approach distinguishes between two situations. First, when quantitative emission data of specific PFAS uses are available, expected additional emissions from a proposed derogation can be quantified straightforwardly. In many cases, however, emission data at sub-use level are largely lacking. In such cases, the expected additional emissions of a proposed derogation are approximated using expert information about the applications covered by a derogation. Such qualitative information includes, for example, information about the environmental release factors applied to certain PFAS groups, or information about the relevance of a certain application in the assessed group of uses. Using the expert judgement allows to estimate additional emissions associated with the relevant derogation. Further details about the approach are provided in section 2.4.3.

Substantiated suggestions for potential alternative regulatory options brought forward during the consultation on the Annex XV report have also been considered by the Dossier Submitters. When these options (as suggested or in an adapted form) have been deemed effective, practical and monitorable and therefore been deemed to constitute a potential valid alternative to the proposed restriction, they are compared to RO1 and RO2 in terms of their proportionality. This refers to options (termed RO3) allowing continued use under strict conditions that minimize emissions over the full life cycle, i.e. regulatory options potentially allowing for adequate control of risks through means other than a ban.

In some cases, restriction options with complementary emission reducing measures and requirements attached to use-specific derogations under RO2 have also been considered with a view of improving the effectiveness of the restriction option. Where relevant, such additional restriction options have been assessed in a dedicated section within the sector-/use-specific assessment in Annex E.

### 2.3.2. **Proposed restriction option**

A detailed description of the proposed Annex XVII entry text is available in the summary at the beginning of this dossier. This proposed entry text is equivalent to RO2, i.e., a ban with use-specific derogations of a duration of five or 12 years after the transition period of 18 months ends and including some time-unlimited derogations for exceptional cases based on practical considerations.

# 2.4. Assessment of the restriction options

## 2.4.1. Economic and other impacts

### 2.4.1.1. Economic impacts on producers and customers and other impacts (e.g. employment losses)

As mentioned in section 2.1, costs of ROs include various components including producer surplus losses of directly affected companies, i.e. users of PFASs, as well as companies in the upstream supply chain, consumer surplus losses as a result of changes to the product price, welfare losses and/or additional costs resulting from changes in the characteristics of goods or their absence (where substitution is not feasible) as well as job losses.

The types of costs resulting from different ROs depend on the reaction chosen by affected companies. A company that substitutes, for example, faces Research & Development costs in relation to the identification and testing of relevant alternatives and the reformulation/re-design of the product. The company might, furthermore, face one-off costs for purchasing and installing new equipment, so-called capital costs, if the switch to alternatives makes changes to the production process necessary. In addition, companies might also face changes in operating costs such as changes in raw material costs resulting, for example, from differences in the unit cost of the alternative in comparison to the cost of PFASs and/or a higher volume of the substance being required. Changes to the production process might also result in more energy use with associated cost increases for companies. If such cost increases can be passed on to customers via higher product prices, limited economic impacts on affected companies are expected, while customers will face consumer surplus losses. If the ability to pass on costs to customers is limited, e.g. due to high competition, companies will face producer surplus/profit losses. A company that stops production in response to the restriction also faces producer surplus/profit losses – although at a higher magnitude. In addition, it might face costs in relation to dismantling plants. Where many companies decide to cease operation, welfare losses and/or additional costs to customers due to the absence of certain products on the EU/EEA market might occur in addition to impacts on the economy as a whole as a result of employment losses.

The reaction chosen by the affected company is determined by the technical feasibility of alternatives, their economic feasibility, whether alternatives are available in sufficient quantities and whether the substitution process can be completed in the available timeframe before entry-into-force of a restriction. Where technically feasible alternatives do not exist, company closures will occur. Where technically feasible alternatives exist, substitution is a possible option for affected companies, but it does not guarantee the absence of business closures. Whether substitution is chosen as the preferred reaction by individual companies depends – amongst other factors – on whether individual companies consider it economically viable to them to substitute and whether they consider it possible to find suppliers that can provide the identified alternative in sufficient quantities. Due to differences in, for example, the financial resources of companies, the chosen reaction might differ.

Given the importance of the most likely behavioural reaction of companies for understanding the costs associated with different ROs, this section describes the extent to which technically and economically feasible alternatives are available in different sectors together with the anticipated impacts. Table 10 provides summary information on alternatives as well as the anticipated costs resulting from a full ban of PFASs, i.e. RO1, for all use sectors, while the impacts of RO2 are described in Table 11.

The Dossier Submitters note that impacts related to the manufacturing of PFAS (see details in Annex E.2.1.) are not included in Table 10, Table 11, Table 15, because the application of the general approach chosen by the Dossier Submitters for assessing and comparing RO1 and RO2 is not appropriate for PFAS manufacturing. This is amongst others due to: a) an assessment of the use is only possible, if the impacts resulting from all other uses, i.e. environmental impacts as well as cost impacts partially depend on regulatory measures for all other assessed sectors can be considered; b) manufacturing/production of PFAS has the

sole purpose to produce PFASs. Accordingly, analysis of alternatives for PFASs manufacture as such has no meaning, as manufacturing has no independent function; c) consequently, alternatives cannot become available over time.
Considering these differences, the Dossier Submitters deem it necessary to consider additional restriction options. For more details see Annex E.2.1. However, in order to report the results regarding the assessed ROs in a format similar to the reporting for other uses in the Table 10, Table 11, Table 15, a separate Table 16 for PFAS manufacture is available in 2.4.4.1 including information on environmental impacts, costs and other impacts and proportionality.

For both RO1 and RO2, overall costs are categorized into five categories, to facilitate comparison of the level of costs across assessments, based on the following criteria:

- Costs are classified as **"very low",** when
  - Technically and economically feasible alternatives are available; and
  - The impact assessment indicates that the costs are close to zero, e.g. as only a small number of firms and/or users are affected, and each to a limited extent[30].
- Costs are classified as **"low"**, for all cases where technically and economically feasible alternatives are available that do not fall into the "very low" or "moderate" cost categories.
- Costs are classified as **"moderate"**, when
  - Technically and economically feasible alternatives are available; and
  - The impact assessment indicates that substitution costs will not be low, e.g. due to a large number of firms and/or end users being affected (despite limited impacts at company or individual level), and/or complicated substitution processes.
- Costs are classified as **"very high",** when
  - Substantial social costs due to health or safety implications are expected; and/or
  - Severe impacts on the competitiveness of EEA industry are expected, e.g. PFASs are only relevant for the manufacturing stage of products and not contained in the final product and a ban would thus not affect imports, or market growth is expected to be high at the global level and price is expected to play a role that is beyond average in determining customer's purchasing decisions (with a very limited possibility for EU companies to compete in such markets based on quality arguments).
- Costs are classified as **"high"**, in all other cases, i.e. where feasible alternatives are not available but the implications are not as severe as in the cases for which costs are classified as "very high".

For some of the use sectors, various specific uses are listed but it is important to stress that the use sector is not limited to the uses listed. Further details on the anticipated costs and underlying assessment can be found in Annex E. The relevant section of Annex E for each sector is indicated in the tables.

As explained in section 2.3.1, the strength of evidence is an important criterion considered by the Dossier Submitters in proposing derogations. As such, Table 10 and Table 11 also provide information on the strength of the underlying evidence, whereby evidence can consist of (a combination of) (i) literature, (ii) stakeholder information from the CfE (carried out in 2020), the 2nd stakeholder consultation (carried out in 2021), targeted stakeholder interviews

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[30] Impacts are deemed to be limited when they are not so large that they would lead to a change in use of the product or behaviour of the user, e.g. price changes are so small that they would not lead customers to reconsider whether to purchase the product or the impact on functionality is so small that it is not deemed to affect end user behaviour with respect to the frequency of use.

and/or the consultation on the Annex XV report (carried out from March to September 2023), (iii) precedence[31], principles[32], consistency arguments (e.g. with other regulations or guidance documents), as well as defaults, and (iv) expert judgement. Considered aspects include the quality of evidence, e.g. the representativeness of samples underlying quantitative information, the extent of evidence available from one or different lines of evidence and the extent to which available evidence corroborates or contradicts itself.

The Dossier Submitters distinguish between the following levels of evidence:

- **Sufficiently strong evidence:** Good evidence from one or more lines of evidence, where conflicting information can be explained and reconciled;
- **Weak evidence:** Insufficient information has been identified, or received from consultation, to establish a firm conclusion;
- **Inconclusive evidence:** Conflicting evidence from one[33] or different lines of evidence, where conflicts cannot be explained and reconciled; and
- **No evidence.**

Conclusions based on precedence, principles, consistency arguments, defaults, and assumptions based on expert judgement are considered to be sufficiently strong where they are well-grounded, e.g. in academic theory.

Further details on the strength of evidence associated with different components can be found in Annex E.

The level of evidence regarding the non-existence of alternatives at EiF determines how the Dossier Submitters deal with derogations:

- Only when there is **sufficiently strong evidence**, a derogation is **proposed**.
- When there is **weak evidence**, a derogation was considered to potentially be warranted at the time of submission of the Annex XV dossier in January 2023 and was marked for reconsideration based on additional evidence from the Annex XV report consultation. Where the evidence remains weak, no derogation is proposed.
- When there is **inconclusive evidence** or **no evidence**, a derogation is also not proposed.

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[31] An example of precedence is a case in which the Dossier Submitters conclude that the volume of waste expected to be treated in a certain way, e.g. landfilling instead of incineration or recycling, will decline based on related EU policy targets.

[32] An example of principles is a case in which the Dossier Submitters conclude that demand for products in a certain sector is price inelastic and that companies are therefore expected to pass on possible substitution costs fully to customers, which will limit producer surplus losses at the expense of additional consumer surplus losses. Demand in sectors with mass markets producing goods for the general public (such as the consumer apparel sector) is, for example, deemed to be comparatively price elastic, i.e. deemed to change more in response to a price change, due to price being a key factor considered by customers in their purchasing decision. Demand in sectors producing highly specialised products for industrial and/or professional users is deemed less price elastic. This is the case as such users likely also value other factors such as a longstanding supplier relationship highly. As a result, their purchasing decision is likely less dominated by price considerations.

[33] Conflicting evidence from one line of evidence refers, for example, to different literature sources that come to conflicting conclusions or conflicting information provided by stakeholders.

**Table 10. RO1 - Summary table of alternatives and cost impacts for PFAS use sectors resulting from a full ban of PFASs.**

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| **TULAC (Annex E.2.2.)**[34] | | |
| **Sector as a whole (excluding technical textiles)**<br>Fluoropolymers account for the majority of the use of PFASs in TULAC. | • Sufficiently strong evidence that technically feasible alternatives exist for (i) home textiles, (ii) consumer apparel, (iii) professional apparel, (iv) leather applications, and (v) home fabric treatments<br>• Sufficiently strong evidence that technically feasible alternatives do not exist for PPE as a whole<br>• Sufficiently strong evidence pointing to the economic feasibility of alternatives for (i-ii) home textiles and consumer apparel (in the form of practical examples of completed substitution), (iii) professional apparel (e.g. in the form of information pointing to the proven use of alternatives for professional sportswear and footwear and strong evidence for consumer apparel applications, which are deemed to be comparable to some extent), (iv) leather applications (e.g. due to sufficiently strong evidence for consumer apparel which suggests that the alternatives identified as suitable for leather applications are economically feasible and reported ongoing substitution activities), and (v) home fabric treatments (in the form of evidence for the existence of alternative-based products on the market)<br>• No evidence pointing to a shortage in supply<br>• Conclusion: High substitution potential at EiF for home textiles, consumer apparel, professional apparel, leather applications and home fabric treatments [sufficiently strong evidence] and low substitution potential at EiF for PPE [sufficiently strong evidence] | • Between around 4 700 and 24 800 companies are estimated to be affected by a restriction in relation to home textiles, consumer apparel, professional apparel and PPE as well as leather. Information on the number of affected companies producing home fabric treatments is not available.<br>• Producer surplus losses as a result of business closures (in comparison to other TULAC sub-sectors) are expected to be minor for home textiles (and largely offset by gains of other companies due to a high offsetting potential), medium for consumer apparel (but largely offset by gains of other companies due to a high offsetting potential), medium for professional apparel and PPE (with considerable additional producer surplus losses in the wider supply chain in contrast to other sub-sectors), minor in relation to leather and minor for home fabric treatments.<br>• Producer surplus losses as a result of substitution (in comparison to other TULAC sub-sectors) are (expected to be) medium for home textiles, major for consumer apparel, minor for professional apparel and PPE, minor in relation to leather and unknown for home fabric treatments.<br>• Consumer surplus losses resulting from price changes associated with substitution in comparison to other TULAC sub-sectors are (expected to be) |

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[34] Note that the terms minor/medium/major used here are not the same as the qualitative cost descriptors defined in Step 5 of Table E.1 in Annex E. The use of minor/medium/major here should be read as indicative of the differences in impacts expected for the TULAC sub-sectors, respectively. The cost conclusion in line with the general qualitative cost descriptors is provided at the bottom of the text.

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | medium in relation to home textiles, major in relation to consumer apparel, minor in relation to professional apparel and PPE, minor in relation to leather and unknown in relation to home fabric treatments.<br>• High welfare losses or additional costs as a result of lower functionality are expected, e.g. as a result of (i) the absence of sufficiently protective PPE (which would also have a reduced service life duration) due to no technically feasible alternatives being known and (ii) earlier disposal of PPE as a result of the unavailability of impregnation agents; a small reduction in water repellence (which seems however to be acceptable for customers in most cases according to stakeholder information); welfare losses and/or additional costs (such as increased cleaning and replacement costs) due to lower oil and dirt repellence, e.g. in relation to upholstery in public settings, sportswear and footwear, and in relation to leather applications; and additional costs resulting from high replacement frequencies or more frequent re-impregnation due to the lower ability of alternatives to withstand household laundering or dry cleaning.<br>• Employment losses are expected, mainly in relation to the manufacture of professional apparel and PPE. Information from the consultation on the Annex XV report suggests that at least 26 702 jobs are at risk in the five sub-sectors, with over 95% of those being related to the professional apparel and PPE industry.<br>• Overall, the cost associated with RO1 in relation to PPE alone is estimated as an annuity cost of €4.017 billion per year in the consultation on the Annex XV report (which accounts for lost profits and employment impacts). |

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| | | Conclusion: Very high costs |
| **Food contact materials and packaging (Annex E.2.3.)** | | |
| **Sector as a whole** | • There is sufficiently strong evidence that technically and economically feasible alternatives exist for (i) PFASs used in paper and board used for packaging, (ii) substitution of f-HDPE containers used, for example, for storage of plant protection products, and (iii) PFASs used in non-stick surfaces in consumer cookware and domestic appliances.<br>• There is no evidence that substitution potential on the grounds of technical and economic feasibility would be problematic for (i) inks, lacquers and waxes used in printing for food contact materials, and (ii) miscellaneous packaging applications such as coatings for beverage cans and car wraps.<br>• There is sufficiently strong evidence that technically and economically feasible alternatives do not exist in a significant share of applications regarding (i) polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) and (ii) PFASs used in non-stick surfaces in industrial bakeware.<br>Conclusion: High substitution potential at EiF for PFASs used in paper and board used for packaging, for substitution of f-HDPE containers, for PFASs used in non-stick surfaces in consumer cookware and domestic appliances [all with sufficiently strong evidence] and for inks, lacquers and waxes used in printing for food contact materials, and miscellaneous packaging applications [both with no evidence that alternatives are unavailable]. There is low substitution potential at EiF for polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) and PFASs used in non-stick surfaces in industrial bakeware [sufficiently strong evidence]. | A large number of companies are active in this sector, working in the production, distribution and sales of food and other goods, manufacturing and use of packaging materials, and the production of kitchen wares. The baked goods sector alone generates sales of €83 billion in the EU annually.<br>Available evidence suggests the following on costs associated with a full ban and a transition period of 18 months:<br>Low costs are estimated for substitution in the sub-sectors paper and board packaging; f-HDPE packaging; inks, lacquers and waxes used for printing on food packaging; and for miscellaneous packaging applications (beverage cans and car wraps).<br>Moderate costs are estimated for substitution with a transition period of 18 months in the sub-sector non-stick domestic cookware and appliances, noting that whilst some firms have already transitioned from PFAS coatings others remain dependent upon them. The potential for job losses was raised by trade associations and some businesses.<br>Very high costs are estimated for substitution with a transition period of 18 months in the production of plastic film and sheet for packaging given a lack of proven alternatives to PFAS PPAs at the present time that are compatible with existing production lines, and given the importance of plastics in packaging; and for substitution of non-stick surfaces in industrial bakeware. In both cases there is a need for significant R&D against a range of operating conditions and different product types. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | Consumer losses are considered low for all applications except use of PPAs in production of plastic film and sheet and use of PFAS in non-stick coatings for industrial bakeware.<br>Conclusion: Very high costs |
| **Metal plating and manufacture of metal products (Annex E.2.4.) [35]** | | |
| **Hard chrome plating**<br>Fluoropolymers are not used in the process of hard chrome plating.<br>Note: The terms 'functional chrome plating' and ''hard chrome plating' are used interchangeably throughout the background document. These are assumed to concern the same use. 'Hard chrome plating' is subsumed under the term 'functional chrome plating' throughout the document and vice versa. | Sufficiently strong evidence that technically and economically feasible alternatives are not generally available.<br>Conclusion: Low substitution potential at EiF. | Alternatives are not readily available at EiF. A ban would lead to social costs due to health implications for the workforce in the hard chrome industry. Also impact on the competitiveness of EEA industry is expected.<br>Sufficiently strong evidence that there will be high to very high costs to the hard chrome plating industry from a ban.<br>Conclusion: High to Very high costs. |

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[35] The use of PFASs used for the production of parts for use in engines and other applications in technical compartments, etc. is covered under transport applications.
The use of PFASs used for the production of parts for use in machinery is, as other industrial applications such as sealings, covered in a separate section.
The use of PFASs used for the production of parts for military equipment is covered under applications of PFASs in the military context.
The use of PFASs used for coil coating of metals is covered under construction applications
The use of PFASs used as cover gases for use in magnesium casting is covered under fluorinated gases.
The use of PFASs used as oils and lubricants is covered under lubricants.

| Use sector | Alternatives | Cost impact |
|---|---|---|
| **Decorative chrome plating with chrome, chrome plating on plastics and plating with metals other than chrome**<br>Fluoropolymers are not used in the process of decorative chrome plating and chrome plating on plastics.<br>Fluoropolymers are used in plating processes with metals other than chrome. | Sufficiently strong evidence that technically and economically feasible alternatives are generally available for decorative chrome plating.<br>Conclusion: High substitution potential at EiF.<br>Weak evidence that technically and economically feasible alternatives are generally available for chrome plating on plastics and nickel plating.<br>Conclusion: Not possible to conclude on the substitution potential at EiF.<br>Weak evidence that technically and economically feasible alternatives are not generally available for aluminium anodizing, and plating with other metals.<br>Conclusion: Not possible to conclude on the substitution potential at EiF. | Sufficiently strong evidence that there will be low costs to the decorative chrome plating industry from a ban.<br>Conclusion: Low costs.<br>Not enough evidence to draw conclusions on cost impacts on the chrome plating on plastics, nickel plating, aluminium anodizing, and plating with other metals sectors.<br>Conclusion: No evidence on costs. |
| **Manufacture of metal products not addressed elsewhere**<br>Mainly fluoropolymers are used in manufacture of metal products. | Sufficiently strong evidence that technically and economically feasible alternatives are generally available for razor blades.<br>Conclusion: High substitution potential at EiF.<br>Weak evidence that technically and economically feasible alternatives are generally available for coatings in metal manufacturing.<br>Conclusion: Not possible to conclude on the substitution potential at EiF.<br>Weak evidence that technically and economically feasible alternatives are generally available for use as solvents in metal manufacturing (excluding cleaning of PFAS-containing lubricants). For cleaning of PFAS-containing lubricants there is weak evidence that technically and economically feasible | Concerning razor blades, the information on cost data is considered as weak. Evidence received in the consultation on the Annex XV report is inconclusive. No robust information is available that suggests higher than low costs resulting from a substitution with alternative dry or wet shaving products.<br>Conclusion: Very low to low costs.<br>Not enough evidence to draw conclusions on cost impacts for coating and solvents in metal manufacturing.<br>Conclusion: No evidence on costs. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | alternatives are not generally available.<br>Conclusion: Not possible to conclude on the substitution potential at EiF. | |
| **Consumer mixtures and miscellaneous consumer articles (Annex E.2.5.)** | | |
| **Sector as a whole**<br>Fluoropolymers potentially account for small share of use in consumer mixtures and very large share of use in miscellaneous consumer articles. | Sufficiently strong evidence that technically and economically feasible alternatives exist for:<br>• Cleaners (for glass, metal, ceramic, carpet and upholstery)<br>• Waxes and polishes (for e.g. furniture, floors and cars)<br>• Dishwashing products (as rinse aid)<br>• Windscreen treatments for automobiles and also windscreen wiper fluids<br>• Strings for musical instruments<br>• Fishing lines<br>No evidence that technically feasible alternatives do not exist for:<br>• Anti-fogging agent for goggles and spectacles<br>• Use in pianos | **Consumer mixtures:**<br>No information is available that suggests significant additional costs resulting from price differences for alternatives. Temporary reduction in producer surplus resulting from substitution costs is possible. The extent is unclear but no information points to costs that impact manufacturers significantly. Consumer surplus losses resulting from functional losses are possible. No information is available that questions the Dossier Submitters' initial assessment that sufficiently effective alternatives for all uses are available.<br>Conclusion: Very low to low costs<br>**Miscellaneous consumer articles:**<br>Musical instruments:<br>Producer surplus losses as a result of loss of export business possible, due to not being able to compete with non-EEA manufacturers of PVDF strings. Consumer surplus losses due to functional losses.<br>Conclusion for musical instruments: Low costs<br>Fishing lines:<br>No data is available that suggests costs for manufacturers. Available information focuses on impacts on users.<br>Based on robust data some consumer surplus losses in relation to durability of the alternative fishing lines |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | can be expected. Less durable fishing line can lead to more frequent need for replacement and less fishing success.<br>Conclusion for fishing lines: Very low to low costs<br>Overarching conclusion for miscellaneous consumer articles: Low costs<br>Overarching conclusion covering both consumer mixtures and miscellaneous consumer articles: Low costs |
| **Cosmetics (Annex E.2.6.)** | | |
| **Cosmetic products**<br>Some use of fluoropolymers in cosmetic products. | Sufficiently strong evidence that technically and economically feasible alternatives exist.<br>No evidence pointing to a shortage in supply of alternatives.<br><u>Conclusion:</u> High substitution potential at EiF [sufficiently strong evidence] | Net product reformulation costs estimated to be €13.1 million over the time period 2025-2055.<br>No information indicating that substance substitution costs would be a barrier to implementation of the proposed restriction. The Dossier Submitters assume that these costs are negligible.<br>No information available indicating any significant losses in product performance. The Dossier Submitters assume that the associated losses for consumers are non-existent or negligible.<br><u>Conclusion:</u> Low costs. |
| **Peptide synthesis for cosmetic applications**<br>No reported use of fluoropolymers in peptide synthesis. | Inconclusive evidence on whether there are technically feasible alternatives.<br><u>Conclusion:</u> Unclear substitution potential at EiF [inconclusive evidence] | Some degree of development of peptide synthesis processes is expected. The Dossier Submitters have no information on the costs associated with such process development. The Dossier Submitters also lack information on the number of peptides manufactured using PFAS that would require process development.<br>Net product reformulation costs for downstream cosmetics producers using non-PFAS peptides of €9.2 million are expected over the time period 2025-2055. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | No changes in operating costs expected.<br>Conclusion: Low costs. |
| **Ski wax (Annex E.2.7.)** | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to ski wax is minor. | Sufficiently strong evidence that technically and economically feasible alternatives exist.<br>No evidence pointing to a shortage in supply of alternatives.<br>Conclusion: High substitution potential at EiF [sufficiently strong evidence] | Lower consumer expenditure on ski wax is likely. This reduction in expenditure could lead to a reduction in producer surplus, the extent of the latter is however unclear.<br>Loss in consumer surplus expected to be negligible.<br>Costs relating to testing, equipment, occupational safety measures and product development are not expected.<br>Conclusion: Very low costs |
| **Applications of fluorinated gases (Annex E.2.8.)**<br>*Note that mobile air conditioning, heat pump systems (MAC) and transport refrigeration are covered under Transport below.* | | |
| **Sector as a whole** | There is sufficiently strong evidence that there is a high substitution potential at EiF for:<br>• The majority of domestic, commercial and industrial refrigeration applications;<br>• The majority of domestic, commercial and industrial (stationary) air conditioning and heat pump applications;<br>• Heat pumps in tumble driers;<br>• Many applications of foam blowing agents;<br>• The majority of applications of propellants;<br>• Cover gases used for magnesium diecasting (and weak evidence for sand casting);<br>• Many applications of clean fire suppressants; and<br>• Insulating gas in electrical equipment for applications up to 145 kV.<br>There is furthermore sufficiently strong evidence that there is a low substitution potential at EiF for:<br>• Refrigerants in low temperature refrigeration below –50 °C;<br>• Refrigerants in laboratory test and measurement equipment; | Available evidence suggests that the costs associated with a full ban and a transition period of 18 months are:<br>• Very high in relation to refrigeration (as a result of the absence of alternatives for some specific applications, which could lead to some impacts on healthcare services, and challenges in relation to the maintenance of existing systems);<br>• Very high in relation to air conditioning and heat pumps (as a result of the absence of alternatives for cases where local or national building codes limit the use of alternatives for air conditioning and heat pumps, the potential health impacts associated with that and challenges in relation to the maintenance of existing systems);<br>• Very high in relation to foam blowing agents (as a result of the absence of alternatives with a suitable performance |

| Use sector | Alternatives | Cost impact |
|---|---|---|
|  | • Refrigerants in refrigerated centrifuges used, for example, in medical laboratories;<br>• Relevant applications at the CERN site;<br>• Stationary air conditioning applications, where safety standard or building codes limit the use of alternatives;<br>• Several applications of foam blowing agents;<br>• Several applications of propellants;<br>• Some specific applications of clean fire suppressants, e.g. in aviation, data centres, historical archives and museums;<br>• The preservation of cultural paper-based materials; and<br>• High-voltage switchgear >145kV.<br>In addition, there are no drop-in alternatives for use in existing equipment in relation to:<br>• Domestic, commercial and industrial refrigeration;<br>• Domestic, commercial and industrial (stationary) air conditioning and heat pumps;<br>• Fire suppressants; and<br>• Existing switchgear equipment using insulating gas. | and/or risk profile for some applications and particularly the health & safety impacts resulting from the use of alternatives with a higher risk of flammability);<br>• Very high in relation to propellants (as a result of the absence of alternatives with a suitable hazard/risk and performance profile for some applications and particularly the health & safety impacts and impacts on competitiveness that are associated with the use of alternatives);<br>• Low in relation to cover gases (as alternatives are already widely used and as alternatives should be readily implementable);<br>• Very high in relation to clean fire suppressants (as a result of the absence of alternatives for some applications and the associated health & safety impacts, the wider economic impacts as well as the challenges in relation to the maintenance of existing sytems);<br>• High in relation to the preservation of cultural paper-based materials (as a result of the absence of alternatives); and<br>• Very high in relation to insulating gas in electrical equipment (as a result of the absence of alternatives and the significant impacts on the wider society in terms of energy transmission).<br>Conclusion:<br>As such, the overall costs associated with RO1 for all relevant applications of fluorinated gases are concluded to be:<br>Very high |

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| **Medical devices (Annex E.2.9.)** | | |
| **Implantable medical devices** (including medical implants and meshes) | Sufficiently strong evidence that technically and economically feasible alternatives are not generally available.<br>Conclusion: Low substitution potential at EiF [sufficiently strong evidence] | Very high socio-economic costs can be expected from the public health effects if unavailable. |
| **Wound treatment products (non-implantable/non-invasive medical devices)** | Weak evidence that technically and economically feasible alternatives are generally available.<br>Conclusion: Substitution potential is uncertain. | No information was provided on the cost impacts of a ban, therefore the costs are unknown. |
| **Invasive medical devices (e.g. tubes and catheters)** | Sufficiently strong evidence that technically and economically feasible alternatives are not generally available.<br>Conclusion: Low substitution potential at EiF [sufficiently strong evidence] | The information obtained indicates that a ban on PFASs in these applications would lead to negative effects on patients. The socio-economic costs related to these implications can be expected to be very high. |
| **Other coating applications (non-implantable medical devices)** | Weak evidence that technically and economically feasible alternatives are generally available.<br>Conclusion: Substitution potential is uncertain. | For other coating applications, there was no information provided on the cost impacts of a ban, and therefore the costs are unknown. |
| **Sterilization gases** | A wide range of economically feasible sterilization methods are available, and there is sufficiently strong evidence regarding their technical feasibility in the applications where PFASs are currently used.<br>Conclusion: High substitution potential at EiF [sufficiently strong evidence] | If any of the identified sterilization methods is technically feasible for the applications where PFASs are currently used, the cost impacts of a full ban are expected to be low. |
| **Packaging of medical devices** | Sufficiently strong evidence that technically and economically feasible alternatives are not generally available for the following packaging of medical devices:<br>• PCTFE-based packaging for medical devices<br>• Use of PPAs in flexible packaging for medical devices.<br>For other packaging of medical devices, there is no information on alternatives.<br>Conclusion: Low substitution potential at EiF for some packaging applications for medical devices using PCTFE and/or PPAs in flexible packaging [sufficiently strong evidence] | In conclusion, the Dossier Submitters consider that there is weak evidence (in terms of socioeconomic data on costs associated with a ban on packaging of medical devices) and the Dossier Submitters were unable to establish a firm conclusion on the classification of costs. However, in applications where packaging is vital for functionality and safety, and where no available alternatives exist that meet the technical requirements, there is sufficiently strong evidence that a ban on PFASs is likely to have high socio-economic costs. The Dossier Submitters do not have sufficient information available to identify these applications. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | In applications where packaging is not vital for the functionality and safety of the medical devices or where available alternatives can meet the technical requirements for functionality and safety, the Dossier Submitters assume that a ban of PFASs would have low socio-economic costs. |
| **Transport (Annex E.2.10.)** | | |
| **Uses of fluoropolymers and perfluoropolyethers in transport vehicles[36] (excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles)**<br>Use of fluoropolymers. | There are currently no alternatives that can provide the same combination of properties as fluoropolymers or perfluoropolyethers.<br>This means that alternatives are not suitable where such a combination of properties is fundamental to achieving required functionality or performance in the vehicle.<br>Therefore, there is sufficiently strong evidence that technically feasible alternatives are not available for some of the affected applications.<br>For other applications there is weak evidence that technically feasible alternatives may be available.<br>The Dossier Submitters are not in a position to distinguish between the applications that belong to these two categories with the evidence that is available.<br>The Dossier Submitters cannot exclude that for some of the applications where technically feasible alternatives are not available fluoropolymers and/or perfluoropolyethers are fundamental to ensure the safety and/or the environmental | In relation to applications for which the substitution potential is high, a ban could still lead to an increase in cost or a loss in the functionality of a transport vehicle. In these cases, EEA manufacturers would suffer from a reduction in competitiveness on the export market and EEA customers might face higher prices for vehicles and/or vehicles of lower quality.<br>As there are however also applications for which the substitution potential is low, the Dossier Submitters assume that the supply of transport vehicles to the EEA market would be severely affected by a ban on PFASs. This would likely lead to substantial socio-economic costs both for the affected component manufacturers, transport vehicle manufacturers and for the users of vehicles.<br>Conclusion: Very high costs |

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[36] This includes: Foam mouldings; Tubes and hoses in combustion engine systems; Protective coatings and paints for transport vehicles; Hydrophobic coatings for windshields; Cable liners & coatings for transport vehicles, including high-voltage insulators; Anti-fouling coatings for ships; Surface coatings for exterior sensors; Anti-icing coating for helicopter rotors; Trim materials for vehicle interiors; Coating of insulation materials; Coatings to reduce fuel consumption and emissions; FEP based heat shrink sleeving; Liners for aerospace hoses; and Wrap for aluminium fan cases for jet engines.

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| | performance of transport vehicles (e.g. aspects of vehicle performance within the remit of EU vehicle type approval legislation, where this exists).<br>Conclusion<br>Suitable alternatives are not available for at least some applications of fluoropolymers and perfluoropolyethers in transport vehicles. Therefore, there is low substitution potential at EiF [sufficiently strong evidence].<br>For other applications of fluoropolymers and perfluoropolyethers in transport vehicles, there are indications that technically feasible alternatives are available and for these the substitution potential is high [weak evidence].<br>However, due to limited specific information, it is not possible to reliably distinguish which applications have high versus low substitution potential.<br>The Dossier Submitters cannot exclude that for some of the applications where the substitution potential is low, fluoropolymers and/or perfluoropolyethers are fundamental to ensure the safety and/or the environmental performance of transport vehicles. | |
| **Reflective coatings for traffic signs**<br>Use of fluoropolymers. | There is no evidence on whether or not technically feasible alternatives exist for this use.<br>Conclusion: The substitution potential at EiF is unknown [no evidence]. | The information received in the call for evidence (CfE), the 2nd stakeholder consultation and the consultation on the Annex XV report does not provide a clear indication of the economic or other impacts of a restriction of PFAS in relation to this use.<br>Conclusion: There is not enough evidence to draw any conclusions on the costs |
| **Additives to hydraulic fluids in transport vehicles**<br>No use of fluoropolymers. | The alternatives do not meet the required combined properties of a fluorinated corrosion inhibitor [sufficiently strong evidence].<br>Conclusion: Low substitution potential at EiF [sufficiently strong evidence] | According to stakeholder submissions, several type approval standards for aircrafts could not be met if the use of PFASs was restricted.  The supply of aircraft and aviation services to the EEA market would be severely affected. Implications for other vehicles are unknown to the Dossier Submitters. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | Conclusion: Very high costs. |
| **Devices for motion control solutions**<br>No use of fluoropolymers. | There is no evidence on whether or not technically feasible alternatives exist for this use.<br>Conclusion: The substitution potential at EiF is unknown [no evidence]. | The information received in the call for evidence (CfE), the 2nd stakeholder consultation and the consultation on the Annex XV report does not provide a clear indication of the economic or other impacts of a restriction of PFAS in relation to this use.<br>Conclusion: There is not enough evidence to draw any conclusions on the costs. |
| **Mobile Air Conditioning (MAC) and heat pump systems**<br>No use of fluoropolymers. | There is sufficiently strong evidence that alternatives are available for light duty electrical vehicles, but not yet in the mass market.<br>There is sufficiently strong evidence that there is not yet alternatives for all vehicles other than light duty electrical vehicles. This would include all other means of transport including heavy duty electrical vehicles, combustion engine vehicles and hybrids, trains, ships, airplanes and spacecraft.<br>There is sufficiently strong evidence that technically feasible alternatives are not available for the maintenance/repair, including refilling of existing MAC equipment originally designed to use PFAS.<br>Conclusion: Low substitution potential at EiF [sufficiently strong evidence]. | Impacts on manufacturers in relation to new equipment: MAC systems that use alternatives to PFAS are already on the market for certain light duty electrical vehicle models from frontrunner companies. For manufacturers of other vehicles, and manufacturers of light duty electrical vehicles that are not frontrunner companies, it is mainly in R&D, piloting or upscaling processes, and the vehicles with MAC systems not running on PFAS are not available in sufficient amounts for the mass market at EiF. According to several stakeholders, manufacturers who are not able to supply the market by EiF are likely to close down their business. For most applications, producer surplus losses if a ban was enforced at EiF are likely to be significant.<br>Impacts on end-users in relation to new equipment: For most applications, the impacts for end users would be severe, as the manufacturers would not be able to meet the demand in the market for new vehicles with MAC systems not running on PFAS. This implies that the loss of consumer surplus will be very high. The loss of consumer surplus would be partially offset by the consumer surplus for end-users that can purchase vehicles running on alternatives. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | Impacts in relation to existing equipment: An inability to maintain and refill existing MAC equipment would lead to premature redundancy of equipment with significant additional costs for end-users not being able to use their vehicles, and an increased environmental burden associated with replacing the premature redundant vehicles. [sufficiently strong evidence].<br>Conclusion: Very high costs. |
| **Transport refrigeration**<br>No use of fluoropolymers. | There is sufficiently strong evidence that alternatives exist for both marine and land-based applications (active and passive $CO_2$ systems and $NH_3$ systems). However, these require re-design of equipment as alternatives are not drop-in replacements for PFASs. There is evidence that redesign would need to go beyond cooling systems to wider redesign, for example of lorry tractor and trailer units to provide sufficient space for $CO_2$ based systems.<br>Overall, there is sufficiently strong evidence that technically and economically feasible alternatives to PFAS at EiF are available for marine applications.<br>There is sufficiently strong evidence that technically feasible alternatives are not available for transport refrigeration for other than marine applications, including automotive, rail and aerospace industries.<br>There is sufficiently strong evidence that technically feasible alternatives are not available for the maintenance/repair, including refilling of existing transport refrigeration equipment originally designed to use PFAS.<br>Conclusions:<br>High substitution potential at EiF for marine applications [sufficiently strong evidence]. | Impacts on manufacturers in relation to new equipment: Refrigeration systems that use alternatives to PFAS are already in use for marine applications. It is therefore likely that there is a low loss of producer surplus for marine applications.<br>For applications other than marine applications, systems using alternatives to PFAS have some market penetration, indicating that they can be cost-competitive but there remain significant barriers to widespread adoption. According to several stakeholders, manufacturers that are not able to supply the market with PFAS-free solutions at EiF, will likely close their business. It is therefore likely that there will be a high loss of producer surplus for all applications other than marine applications.<br>Impacts on end-users in relation to new equipment: For marine applications, there will likely be a low loss of consumer surplus. For the other applications, the impacts for end users would be severe, as the manufacturers would not be able to meet the demand in the market for transport refrigeration at EiF. This implies that the loss of consumer surplus will be very high.<br>Impacts in relation to existing equipment: Due to the lack of drop-in alternatives for existing transport refrigeration, a full ban will lead to problems in |

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| | Low substitution potential at EiF for other transport applications [sufficiently strong evidence].<br>Low substitution potential at EiF for maintenance/repair, including refilling of existing transport refrigeration equipment originally designed to use PFAS [sufficiently strong evidence]. | relation to maintenance, repair or refilling of existing equipment. This will lead to premature redundancy of equipment with significant additional costs for end-users for installing a new system and in addition comes the increased environmental burden of replacing the equipment.<br><u>Conclusion:</u> Very high costs. |
| **Electronics and semiconductors (Annex E.2.11.)** | | |
| **Sector as a whole** (Electronics and semiconductors)<br>Fluoropolymers account for the majority of the use of PFASs in relation to the energy sector. | There is sufficiently strong evidence that substitution potential is high for:<br>• Heat transfer fluids for 1-phase immersion cooling<br>There is sufficiently strong evidence that substitution potential is low for:<br>• Heat transfer fluid for vapor phase soldering<br>• Wires and cables (incl. Connectors)<br>• Insulation material of electronic components<br>• Coating / film of electronic components<br>• Printed circuit boards and antennas<br>• Photonics<br>• Anti-drip agents in plastics of electronic components<br>• Heat transfer fluids for 2-phase immersion cooling<br>• Semiconductor manufacturing<br>• Coating and film on displays and lenses of electronic complex objects<br>There is weak evidence that technically feasible alternatives do not exist for:<br>• Electronic components – all sub-uses except printed circuit boards and antennas<br>• Heat transfer fluids – other applications e.g. cold plate cooling | Overall, the number of companies affected by a restriction in relation to uses in the electronics and semiconductor sectors cannot be estimated because not only semiconductor and electronics manufacturers will be affected but also industrial and professional users of electronics, semiconductor and related equipment. A high share of cost impacts is related to the unavailability of high performance electronic and semiconductor articles that are necessary for the proper functioning of an unknown but very large number of complex articles.<br>The costs for society are unknown but expected to be related to the unavailability of an unknown but very high number of electronic articles.<br>Available evidence suggests that the costs associated with a full ban and a transition period of 18 months are:<br>Major in relation to (vacuum) vapor phase soldering / condensation soldering<br>Major in relation to wires and cables (including connectors)<br>Major in relation to insulation material of electronic components (excluding wires and cables)<br>Major in relation to coating / film of electronic components |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | Medium to major in relation to printed circuit boards<br>Medium to major in relation to antennas<br>Major in relation to photonics<br>Major in relation to anti-drip agent<br>Medium to major in relation to 2-phase immersion cooling<br>Major in relation to PFAS used for the manufacturing of semiconductors<br><br>Conclusion: Very high costs. |
| **Energy sector (Annex E.2.12.)** | | |
| **Sector as a whole**<br>Fluoropolymers account for the majority of the use of PFASs in relation to the energy sector. | There is sufficiently strong evidence that substitution potential is high for:<br>• coating of wind turbines (blades and tower)<br><br>There is sufficiently strong evidence that substitution potential is low for:<br>• fuel cells and electrolysis technology<br>• binders and electrolytes in batteries<br>• separator coatings for batteries<br>• front- and backsheets of photovoltaic cells<br><br>There is weak evidence that technically feasible alternatives do not exist for:<br>• PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers<br><br>There is no evidence available on whether technically feasible alternatives exist for:<br>• ETFE in enclosed trough technology (solar collectors) in the field of renewable energy | Overall, the number of companies affected by a restriction in relation to energy uses cannot be estimated because not only upstream manufacturers in the energy sector will be affected but also downstream manufacturers. A high share of cost impacts is related to the unknown but large increase in energy uses that rely on the use of PFAS in the future.<br><br>Available evidence suggests that the costs associated with a full ban and a transition period of 18 months are:<br>• Very high in relation to fuel cells and electrolysis technology;<br>• High in relation to photovoltaic cells;<br>• Very high in relation to binders and electrolytes in batteries;<br>• Very high in relation to PTFE nozzles in load break switches;<br>• Very low to Low in relation to wind energy (coating of wind turbines (blades and tower));<br>• Very low in relation to ETFE in enclosed trough technology (solar collectors) in the field of renewable energy.<br>As such, the overall costs associated with RO1 for all relevant applications are concluded to be: |

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| | | Conclusion: Very high costs |
| **Construction products (Annex E.2.13.)** | | |
| **Sector as a whole**<br>Fluoropolymers account for the majority of the use of PFASs in relation to construction products.<br>More specifically, fluoropolymers account for:<br>• The majority of the use of PFASs in architectural coatings and paints;<br>• The entire use of PFASs in relation to coil coating, where primarily PTFE is used;<br>• A large share of the use of PFASs as polymer additives used for fire safety purposes, for which the use of non-polymeric PFASs also plays a significant role;<br>• The entire use of PFASs in film/foil for greenhouses, where ETFE is used;<br>• The entire use of PFASs in relation to processing aids for production of non-PFAS polymers/plastics;<br>• The entire use of PFASs in relation to bridge and building bearings; | • Sufficiently strong evidence that technically feasible alternatives exist for (i) architectural coatings and paints, (ii) coil coating, (iii) film/foil for greenhouses, (iv) window frames, (v) surface protection, (vi) wetting/levelling agents, in e.g. coating, paints and adhesives and (vii) processing aids for the production of construction articles<br>• Sufficiently strong evidence that technically feasible alternatives do not exist for (i) polymer additives used for fire safety purposes and (ii) bridge and building bearings<br>• Weak evidence suggesting that technically feasible alternatives might not exist for (i) processing aids for production of non-PFAS polymers/plastics, (ii) plumbing applications and (iii) window film manufacturing<br>• For the uses for which technically feasible alternatives have been identified: Sufficiently strong evidence that points to the economic feasibility of the alternatives in the form of evidence for the existence of alternative-based products on the market and/or stakeholder information suggesting that alternatives are cheaper<br>• No evidence pointing to a shortage in supply of alternatives for all uses except plumbing applications: In relation to plumbing applications, there is weak evidence pointing to potential supply shortages in relation to PPSU.<br>Conclusion: | • There is indicative evidence from the consultation on the Annex XV report (used in combination with data from the PRODCOM database) suggesting that PFAS-based products account for 2.5% - 3% of the market in the case of architectural coatings and paints and 4.5% - 5.5% of the market in relation to coil coating. In the absence of comparable indicative evidence from the consultation on the Annex XV report, a market share of 1% - 2% has been assumed for all other uses, except window film manufacturing. Window films are deemed to represent a niche of the PFAS products used within the NACE sector. As such, a market share of 0.5% to 0.75 has been assumed[37].<br>• Based on these assumptions, a ban on PFASs is estimated to impact ~ 10 800 – 15 900 enterprises, including ~ 80 - 100 enterprises in relation to architectural coatings and paints, ~ 7 200 - 8 800 enterprises in relation to coil coating, ~ 480 – 950 enterprises in relation to film/foil for greenhouses and window film manufacturing, ~ 90 – 180 enterprises in relation to bridge and building bearings, and ~ 2 900 – 5 900 enterprises in relation to window frames and ~ 20 enterprises in relation to window film manufacturing. Information on the number of |

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[37] For further justification of this assumption, please refer to Annex E.2.13.

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| • The majority of the use of PFASs in relation to window frames;<br>• The entire use of PFASs in relation to plumbing applications;<br>• A share of the use of PFASs in relation to surface protection, for which both fluoropolymers and side-chain fluorinated polymers are used (but the distribution is unclear);<br>None of the use of PFASs as processing aids for the production of construction articles, for which solely non-polymeric PFASs are used; and<br>• None of the use of PFASs in relation to window film manufacturing, for which only non-polymeric PFASs are used.<br><br>In relation to wetting/levelling agents, primarily non-polymeric PFASs are used. | • High substitution potential at EiF for (i) architectural coatings and paints, (ii) coil coating, (iii) film/foil for greenhouses, (iv) window frames, (v) surface protection, (vi) wetting/levelling agents (in e.g. coating, paints and adhesives) and (ii) processing aids for the production of construction articles [sufficiently strong evidence]<br>• Low substitution potential at EiF for (i) polymer additives used for fire safety purposes and (ii) bridge and building bearings [sufficiently strong evidence]<br>• Weak evidence that the substitution potential might be low for (i) processing aids for the production of non-PFAS polymers/plastics, (ii) plumbing applications and (iii) window film manufacturing | affected companies is not available for the other six uses.<br>• <u>Producer surplus losses</u>: A considerable volume of products manufactured in the EU-27 is expected to be affected by a restriction per year. This includes ~ 123 000 - 148 000 tonnes of architectural coatings and paints, ~ 8 400 – 16 800 tonnes in relation to film/foil for greenhouses, ~ 4 900 – 9 700 tonnes of bridge and building bearings, ~ 2.4 – 4.8 million window frames and ~24 700 – 37 000 tonnes of window films. No information on relevant volumes is available for the same six uses for which the number of affected companies could not be estimated. Information for coil coating is also not available.<br><br>If all companies ceased the manufacture of products, this would result in total annual producer surplus losses of at least ~ €159-245 million, including ~ €35.4-42.5 million in relation to architectural coatings and paints, ~ €52.7-64.4 million in relation to coil coating, ~ €4.1–8.2 million in relation to film/foil for greenhouses, ~ €5.2–10.4 million in relation to bridge and building bearings, ~ €54.5–109 million in relation to window frames and ~ €7.1–10.6 million in relation to window films. This estimate does not account for the producer surplus losses associated with six of the twelve relevant uses due to a lack of data. For one of the uses for which no data is available, i.e. polymer additives used for fire safety purposes, business closure is the most likely behavioural reaction due to sufficiently strong evidence on the absence of alternatives. For two of the uses, i.e. processing aids for the production of non-PFAS polymers/plastics and plumbing applications, the most likely behavioural reaction is unclear due to only weak evidence on the absence |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | of alternatives. As such, only one use (polymer additives used for fire safety purposes) that is deemed to be associated with considerable producer surplus losses as a result of business closures is not accounted for in the above quantitative estimate. At the same time, technically and economically feasible alternatives are available for four of the six uses accounted for in the quantitative estimate of producer surplus losses. For those uses, substitution is the most likely behavioural reaction. The Dossier Submitters therefore consider that the producer surplus losses are lower than the worst-case estimate of ~ €159-245 million provided above.<br>• Consumer surplus losses and other impacts on end-users: The implications for downstream users are expected to include (i) some reduction in the lifetime of architectural coatings and paints, coil coating under harsh environmental conditions, film/foil for greenhouses, window frames, products used for plumbing application, adhesives using wetting/levelling agents, and processing aids for the production of non-PFAS polymers/plastics, which will lead to additional costs for repainting/re-sheeting/more frequent replacement; (ii) some reduction of the resistance against scratches in relation to coil coating; (iii) a decrease in flame retardancy and anti-dripping properties of plastics as a result of the absence of suitable polymer additives, and a potential increase in damage to human life and property; (iv) potentially a certain, but largely acceptable, decrease in fire resistance, in relation to film/foil for greenhouses (for the alternatives PP and PE); (v) additional costs related to, for example, re-lubrication during service life or an unacceptable reduction in lifetime in relation to bridge and building bearings; and (vi) potentially slight differences in oil/soil repellence in relation to surface protection. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | • <u>Other impacts:</u> If all companies ceased operation, this would lead to estimated employment losses in the range of 106 000 to 171 000 jobs, leading to social costs of between €10.5 billion and €16.9 billion. This includes impacts in relation to:<br>(i) architectural coatings and paints, with estimated employment losses of ~ 3 600 – 4 300 jobs and associated social costs of ~ €508-610 million;<br>(ii) coil coating, with estimated employment losses of ~ 48 900 – 59 700 jobs and associated social costs of ~ €4.6-5.7 billion;<br>(iii) film/foil for greenhouses, with estimated employment losses of ~ 13 400 – 26 800 and associated social costs of ~ €1.3-2.7 billion;<br>(iv) bridge and building bearings, with estimated employment losses of ~ 8 300 – 16 500 and associated social costs of ~ €1.4-2.7 billion;<br>(v) window frames, with estimated employment losses of ~ 31 200 – 62 400 jobs and associated social costs of ~ €2.6-5.2 billion and (vi) window film manufacturing, with estimated employment losses of ~ 720 – 1 100 jobs and associated social costs of ~ €102-152 million.<br>The total estimate does not account for the employment losses associated with six of the twelve relevant uses due to a lack of data. For one of the uses for which no data is available, i.e. polymer additives used for fire safety purposes, business closure is the most likely behavioural reaction due to sufficiently strong evidence on the absence of alternatives. For two of the uses, i.e. processing aids for the production of non-PFAS polymers/plastics and plumbing applications, the most likely behavioural reaction is unclear due to only weak evidence on the absence of alternatives. As such, only one use (polymer additives used for fire safety purposes) that is deemed to be associated with considerable business closures is |

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| | | not accounted for in the above quantitative estimate. As substitution is deemed to be a possible option in relation to four of the six uses accounted for in the quantitative estimate, the costs associated with a restriction are however deemed to be lower than the worst-case estimate of between €10.5 billion and €16.9 billion provided above.<br>Conclusion: Very high costs |
| **Lubricants (Annex E.2.14.)** | | |
| **Sector as a whole** | On the basis of the available information, the Dossier Submitters conclude that there is **sufficiently strong evidence** that suitable alternatives are not available for industrial or professional uses of PFAS-containing lubricants or lubricant additives, specifically those that are used under harsh conditions. While the available information suggests that alternatives might be feasible in some specific industrial and professional applications [weak evidence], particularly those that do not take place under harsh conditions, the overall evidence of technical and economic feasibility is insufficient for the Dossier Submitters to distinguish with confidence in which industrial and professional uses alternatives are technically and economically feasible from those where they are not.<br>On the basis of the absence of comments submitted in the consultation on the Annex XV report to the contrary, the Dossier Submitters conclude that there is **sufficiently strong evidence** that there are suitable alternatives for consumer uses of PFAS-containing lubricants or lubricant additives.<br>Conclusion:<br>Suitable alternatives are available for consumer uses. Suitable alternatives are not available for industrial and professional uses, specifically those used under harsh conditions. Therefore, there is **low substitution potential at EiF** for industrial and professional uses of PFAS-containing lubricants or lubricant | Very high costs would arise due to the lack of suitable alternatives at entry into force, specifically for uses under harsh conditions. Functionality loss, e.g. related to performance level and lifetime, is likely to affect an unknown number of industrial and professional users.<br>Product reformulation costs are estimated to range between tens of thousands and several million €, but reformulation will not be possible within the18-month transition period<br>Conclusion; Very high costs. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | additives [sufficiently strong evidence]. High uncertainties remain in relation to the suitability of alternatives in industrial and professional uses [weak evidence]. | |
| **Petroleum and mining (Annex E.2.15.)** | | |
| **Tracers**<br>No reported use of fluoropolymers in tracers. | There is sufficiently strong evidence that technically and economically feasible alternatives are available for **water tracers** without any indications of availability/supply issues.<br>Conclusion: High substitution potential at EiF [sufficiently strong evidence]. As a result, the evidence is sufficiently strong that the substitution potential is high.<br>For **oil and gas tracers**, there is sufficiently strong evidence that technically and economically feasible alternatives are not generally available in sufficient numbers until EiF.<br>Conclusion: Low substitution potential at EiF [sufficiently strong evidence]. As a result, a derogation for oil and gas tracers is proposed and further assessed. | For **water tracers**, the available information indicates that it is a market with a relatively low revenue. In case of a ban, the affected manufacturers are likely to lose revenue, unless they can compensate the revenue losses by selling substitutes. The economic implications for downstream users are expected to be minimal. Changes in operating costs are small or negligible. No transitional costs (reformulation costs, one-off capital costs or administrative costs) have been identified. Functionality losses are expected to be small or negligible, since a range of alternatives with no or limited implications on functionality are available and since PFAS-based water tracers are currently only used in a limited number of applications.<br>Conclusion: Low costs.<br>For **gas and oil tracers**, loss of functionality for downstream users is the main economic impact foreseen. Information from tracer studies is important |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | as a tool for optimising reservoir utilisation in the oil and gas industries as well as for CCS/CCUS. If no tracers – or tracers with poor functionality – are used there will be loss of information on reservoir outflow with implications on overall efficiency of extraction/production for operators, which affects economic productivity of an installation. When a tracer has been used in a well once, the same tracer cannot be used again later as the detection of the tracer substance from previous use would compromise the analyses. Hence, a number of different tracers need to be available for the same application. As only a few technically feasible alternatives have been identified despite substantial research activities into alternatives over several decades, a ban would lead to high costs due to the anticipated functionality losses. Substitution costs and transitional costs for downstream users have not been assessed.<br>Conclusion: High costs. |
| **Anti-foaming agents**<br>No reported use of fluoropolymers. | Sufficiently strong evidence that technically and economically feasible alternatives exist.<br>No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters.<br>Conclusion: High substitution potential at EiF [sufficiently strong evidence]. | The available information indicates that it is a market with a relatively low revenue. In case of a ban, the affected manufacturers are likely to lose revenue, unless they can compensate the revenue losses by selling substitutes.<br>The economic implications for downstream users are expected to be small. PFAS-based agents are more efficient than the alternatives in the production of certain types of crude oils. This requires higher dosage rates for the alternatives, which affects the operating costs, but the overall functionality is not affected. Changes in operating costs are expected due to the higher dosage rates required for the alternatives, but there is no information available to the Dossier Submitters indicating that these increases would be substantial. Transitional costs are expected to be minimal or negligible. No loss in functionality is expected. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | Conclusion: Low costs. |
| **Printing applications (Annex E.2.16.)** | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to printing applications is significant. | • Weak evidence for the existence of a technically feasible alternative for toners for new printers and sufficiently strong evidence that alternatives do not exist for toners used in printers that are already in-use as well as sufficiently strong evidence that a significant amount of time is needed to implement alternatives and offer alternative-based products on the market<br>• Sufficiently strong evidence that technically feasible alternatives do not exist for (i) latex printing inks, (ii) kinetic printing components, (iii) electrophotographic press units and (iv) photosensitive materials<br>• Weak evidence that alternatives do not exist for (i) pigments and colourants and (ii) PTFE powders<br>• No evidence on whether technical alternatives exist for (i) printing plates (offset and letterpress printing), (ii) rollers and (iii) surfactants used in printing equipment<br>• Sufficiently strong evidence that technically and economically feasible alternatives exist for (i) PTFE wax<br>Conclusion: Low substitution potential at EiF for toners, latex printing inks, electrophotographic press units, kinetic printing components and photosensitive materials [sufficiently strong evidence]; low substitution potential at EiF for pigments and colourants and PTFE powders [weak evidence]; unknown substitution potential for printing plates (offset and letterpress printing), rollers and surfactants used in printing equipment as well as high substitution potential at EiF for PTFE waxes [sufficiently strong evidence] | Limited information on the cost impact was obtained from stakeholders. As a result, a semi-quantitative analysis was carried out. The evaluation indicates:<br>• 1 200 to 5 900 enterprises may be affected, many of which are SMEs;<br>• A potential loss of 11 400 to 62 400 jobs, with an associated annual financial impact of €297–1 168 million; and<br>• A loss of €1.8–10.9 billion in annual turnover (and associated producer surplus losses, which will be lower than the turnover losses estimated above as they depend on the profit margin).<br>• Consumer surplus losses could not be determined. However, printed products / items with an annual value of €26 million-4.1 billion might be impacted by a potential ban.<br>The interlinkages between sub-uses mean that the availability of alternatives for one application does not limit the impacts on society as specific printers would remain unavailable in the case of RO1.<br>As such, RO1 results in significant risks of obsolescence that could result in increased waste, job losses, and manufacturer relocation.<br>Conclusion: High costs, given that technically and economically feasible alternatives still need to be identified for most applications. |
| **Sealing applications (Annex E.2.17.)** | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to sealing applications is significant. | • There is **sufficiently strong evidence** to conclude that alternatives do not have the same combination of properties as fluoropolymers and perfluoropolyethers and that where a combination of all or many of the properties of fluoropolymers or perfluoropolyethers are required in a sealing application in | Alternatives are typically cheaper than fluoropolymers. Therefore, in general, such alternatives are deemed to be economically feasible when technically feasible. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
|  | an industrial use to ensure compliance with applicable performance and safety standards then alternatives are not currently technically feasible.<br>• There are indications that alternatives are technical feasible for sealing applications in industrial uses where a combination of only some of the properties provided by fluoropolymers and perfluoropolyethers are required to ensure compliance with applicable performance standards [weak evidence].<br>• No evidence to distinguish with sufficient confidence between specific sealing applications in industrial uses where alternatives are currently technically feasible from industrial uses where they currently are not.<br>• Performance losses associated with the use of a alternatives do not necessarily mean that they are concluded to not be technically feasible. Not enough evidence to identify specific applications where alternatives are considered technically feasible despite certain performance losses.<br>• There is insufficient information [no evidence] to conclude on the technical feasibility of alternatives in professional and consumer uses of sealing applications.<br>Conclusion: **low substitution potential at EiF** [sufficiently strong evidence] for industrial uses of fluoropolymers and perfluoropolyethers in sealing applications which require a combination of all or many of the properties currently provided by these substances.<br>**High substitution potential at EiF** [weak evidence] for industrial uses of fluoropolymers and perfluoropolyethers in sealing applications which require a combination of only some of the properties currently provided by fluoropolymers and perfluoropolyethers.<br>Insufficient information on specific industrial uses of fluoropolymers and perfluoropolyethers in sealing applications to distinguish with sufficient confidence between specific industrial uses where alternatives are currently suitable from those where they currently are not. | Conclusion: High costs, given that technically and economically feasible alternatives still need to be identified for most applications. |

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| | Insufficient information to conclude on the substitution potential of professional and consumer uses of fluoropolymer and perfluoropolyethers in sealing applications. | |
| **Machinery applications (Annex E.2.18.)** | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to machinery applications is significant. | • There is **sufficiently strong evidence** to conclude that alternatives do not have the same combination of properties as fluoropolymers and perfluoropolyethers and that where a combination of all or many of the properties of fluoropolymers or perfluoropolyethers are required in a machinery application in an industrial use to ensure compliance with applicable performance and safety standards then alternatives are not currently technically feasible.<br>• There are indications that alternatives are technical feasible for machinery applications in industrial uses where a combination of only some of the properties provided by fluoropolymers and perfluoropolyethers are required to ensure compliance with applicable performance standards [weak evidence].<br>• No evidence to distinguish with sufficient confidence between specific machinery applications in industrial uses where alternatives are currently technically feasible from industrial uses where they currently are not.<br>• Performance losses associated with the use of a alternatives do not necessarily mean that they are concluded to not be technically feasible. Not enough evidence to identify specific applications where alternatives are considered technically feasible despite certain performance losses.<br>• There is insufficient information [no evidence] to conclude on the technical feasibility of alternatives in professional and consumer uses of machinery applications.<br>Conclusion:<br>**Low substitution potential at EiF** [sufficiently strong evidence] for industrial uses of fluoropolymers and perfluoropolyethers in machinery applications which require a combination of all or many of the properties currently provided by these substances. | Alternatives are typically cheaper than fluoropolymers. Therefore, in general, such alternatives are deemed to be economically feasible when technically feasible.<br>Conclusion: High costs, given that technically and economically feasible alternatives still need to be identified for most applications. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | **High substitution potential at EiF** [weak evidence] for industrial uses of fluoropolymers and perfluoropolyethers in machinery applications which require a combination of only some of the properties currently provided by fluoropolymers and perfluoropolyethers.<br>Insufficient information on specific industrial uses of fluoropolymers and perfluoropolyethers in machinery applications to distinguish with sufficient confidence between specific industrial uses where alternatives are currently suitable from those where they currently are not.<br>Insufficient information to conclude on the substitution potential of professional and consumer uses of fluoropolymer and perfluoropolyethers in machinery applications. | |
| **Other medical applications (Annex E.2.19.)** | | |
| **Fluorinated gases as propellants in pressurized metered-dose inhalers (pMDIs)**<br>No use of fluoropolymers. | Sufficiently strong evidence that there are technically and economically feasible alternatives available. However, given the timelines for regulatory approval and associated studies there is sufficiently strong evidence that the substitution potential is low at EiF. | pMDIs are an important therapeutic option for patients with respiratory illnesses. Nearly 60 million people in Europe live with complex chronic respiratory diseases. A restriction on the use of PFAS propellants in pMDIs that comes into effect while the substitution potential is still low would have a detrimental impact on patients' health with potentially very severe consequences for public health.<br>Conclusion: Very high costs. |
| **Semifluorinated alkanes (SFAs) as excipients in medicinal products for ophthalmic and dermatological therapies**<br>No use of fluoropolymers. | Sufficiently strong evidence that there are no technically feasible alternatives and that the substitution potential at EiF is low. | A restriction of PFAS in this area of use would result in negative impacts for the affected patient groups. However, the Dossier Submitters cannot assess the degree of these public health implications. There are no indications of other substantial impacts of a restriction apart from the loss in functionality and the associated negative impacts on public health.<br>Conclusion: High to Very high costs. |
| **PFAS-coating in release liners and backing film in transdermal patches** | Sufficiently strong evidence that there are no technically feasible alternatives and that the substitution potential at EiF is low. | A restriction would lead to the discontinuation of affected medicinal products or to medicinal products with lower functionality. The number of of patients using transdermal patches is stated to be at least |

| **Use sector** | **Alternatives** | **Cost impact** |
|---|---|---|
| Fluoropolymer use. | | several hundred thousand. The share of these that would be negatively affected by a lower functionality of transdermal patches due to a restriction is uncertain.<br>Conclusion: High to Very high costs. |
| **Fluoropolymers in blisters for solid oral dose formulations**<br>Fluoropolymer use. | Sufficiently strong evidence that there are technically and economically feasible alternatives available. However, given the timelines for regulatory approval and associated studies there is sufficiently strong evidence that the substitution potential is low at EiF. | Blisters with PCTFE are used as immediate packaging of more than 600 pharmaceutical products. A restriction that comes into effect while the substitution potential is still low would result in substantial negative implications for public health.<br>Conclusion: Very high costs. |
| **Fluoropolymer-coated rubber stoppers in vials/flasks for injectable medicinal products**<br>Fluoropolymer use. | Sufficiently strong evidence that alternatives to fluoropolymers are not technically feasible and the substitution potential at EiF is low in at least some applications. For other applications in this area of use, there are indications that technically feasible alternatives to fluoropolymers are available, and that the substitution potential at EiF is high. Due to limited specific information available, the Dossier Submitters cannot distinguish with confidence in which applications alternatives are technically feasible and in which they are not feasible. | Fluoropolymer coated rubber stoppers are widely used. For applications where the substitution potential is low, the availability of the pharmaceuticals would be compromised. The resulting implications on public health are uncertain due to the lack of data, especially since it is not possible to reliably distinguish which applications have high versus low substitution potential.<br>Conclusion: High to Very high costs. |
| **Fluoropolymer-coated packaging of transdermal patches**<br>Fluoropolymer use. | No evidence on the technical and economic feasibility of alternatives and uncertain substitution at EiF. | No relevant information on economic impacts of a restriction of PFAS in this use has been provided in any of the consultations.<br>Conclusion: Uncertain costs. |
| **Fluorinated HDPE packaging**<br>No use of fluoropolymers. | Sufficiently strong evidence that technically and economically feasible alternatives are available, and that the substitution potential at EiF is high. | There is no information indicating that the substitution process is complexy.<br>Conclusion: Very low to Low costs. |
| **Fluoropolymer-coated canisters in pressurized metered-dose inhalers**<br>Fluoropolymer use. | Sufficiently strong evidence that there are no technically feasible alternatives and that the substitution potential at EiF is low. | pMDIs are an important therapeutic option for patients with respiratory illnesses. Nearly 60 million people in Europe live with complex chronic respiratory diseases. A restriction on the use of fluoropolymer-coated canisters in pMDIs that comes into effect while the substitution potential is still low would have a detrimental impact on patients' health |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | with potentially very severe consequences for public health.<br>Conclusion: Very high costs. |
| **Fluoropolymer-coated plungers in pre-filled syringes**<br>Fluoropolymer use. | Sufficiently strong evidence that alternatives to fluoropolymers are not technically feasible and the substitution potential at EiF is low in at least some applications. For other applications in this area of use, there are indications that technically feasible alternatives to fluoropolymers are available, and that the substitution potential at EiF is high. Due to limited specific information available, the Dossier Submitters cannot distinguish with confidence in which applications alternatives are technically feasible and in which they are not feasible. | Fluoropolymer-coated plungers in pre-filled syringes are widely used. For applications where the substitution potential is low, the availability of the pharmaceuticals would be compromised. The resulting implications on public health are uncertain due to the lack of data, especially since it is not possible to reliably distinguish which applications have high versus low substitution potential.<br>Conclusion: High to Very high costs. |
| **PFAS in pre-filled injection pens & autoinjectors**<br>Fluoropolymer use. | Sufficiently strong evidence that alternatives to fluoropolymers are not technically feasible and the substitution potential at EiF is low in at least some applications. For other applications in this area of use, there are indications that technically feasible alternatives to fluoropolymers are available, and that the substitution potential at EiF is high. Due to limited specific information available, the Dossier Submitters cannot distinguish with confidence in which applications alternatives are technically feasible and in which they are not feasible. | PFASs in pre-filled injection pens & autoinjectors are widely used. For applications where the substitution potential is low, the availability of the pharmaceuticals would be compromised. The resulting implications on public health are uncertain due to the lack of data, especially since it is not possible to reliably distinguish which applications have high versus low substitution potential.<br>Conclusion: High to Very high costs. |
| **Military applications (Annex E.2.20.)** | | |
| **Sector as a whole**<br>Use of PFASs (fluropolymers, fluorinated gases) is expected to be significant. | Sufficiently strong evidence that alternatives to PFAS do not exist at EiF for a number of military applications. Whilst it is possible that substitution potential may be higher in some applications included under the scope of 'military applications' long qualification and certification timelines act as barriers to substitution and compromises in performance may result (in military applications) in unacceptable risk to human health/potential loss of life. Due to the supply chain complexity within the military applications sector, the Dossier Submitters cannot conclude for all applications of PFAS however note that in military applications a cautious approach should be taken due to the inherent risks associated with substitution.<br>Conclusion: | Confidentiality of information relating to sensitives sectors such as military applications pose barriers to the derivation of cost impacts and as such no quantified assessment has been conducted by the dossier submitters. Given the complexity and scale of supply chains associated with the military sector it can be expected that costs associated with a restriction of PFAS for military uses would likely pose high to very high costs.<br>Conclusion: Very high costs based on the assumed complexity and scale of the sector alongside limited substitution potential and social costs of health & safety implications. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | **Low substitution potential at EiF** [sufficiently strong evidence] for PFAS used in military applications despite limited visibility across the full sector from data. | |
| **Explosives (Annex E.2.21.)** | | |
| **Sector as a whole**<br><br>Use of fluropolymers (fluoroelastomers) | • Sufficiently strong evidence that alternatives to fluoropolymers used as binders and stabilisers in explosives for military applications do not exist at EiF. Alternatives are required in military applications to provide safe functioning of equipment and ensure risks are minimised. Substitution with poorer performing alternatives would compromise the health & safety of operators.<br>• Weak evidence that alternatives to fluoropolymers do not exist for explosives used in mining and blasting and transport. Data from literature indicate alternative binders to PFAS exist for explosives however not enough data is available to the Dossier Submitters to conclude on their performance or use within the mining and blasting and transport applications.<br>• No evidence that alternatives to fluoropolymers do not exist for explosives used in professional and consumer uses.<br><br>Conclusion:<br><br>**Low substitution potential at EiF** [sufficiently strong evidence] for PFAS used as binders and stabilisers in military explosives.<br><br>Weak evidence of low substitution potential for PFAS used in explosives for mining and blasting and transport.<br><br>No evidence of low substitution potential for PFAS used in explosives in professional and consumer uses. | Costs estimates for explosives are based on a low market share evaluation of publicly available data. For mining and blasting, transport and professional and consumer uses this represents a quantification where substitution potential is low at EiF and presents a worstcase scenario. The total estimated costs are €3.4-4.4 billion/year and one-off social costs of unemployment of €48-61 billion. Based on the uncertainty in the substitution potential not enough evidence is given to draw a conclusion on the cost impacts for these uses.<br><br>No publicly available data was found for military applications of explosives given that confidentiality is high in the military sector. Additionally, only very limited information was shared to the Dossier Submitters relating to economic impacts for the military explosives sector. As such the cost estimate is assumed based on the assumed complexity of supply chains (inferred from the assessment of military applications) and the assumed social costs of health & safety implications which may arise from a lack of alternatives or loss of products from the market. This would result in very high costs.<br>Conclusion: Very high costs. |
| **Technical textiles (Annex E.2.22.)** | | |
| **Sector as a whole** | Sufficiently strong evidence that the substitution potential is high at EiF for:<br>• Outdoor technical textiles<br>• Textiles/membranes and comparable non-textile structures | • Between around 12 400 and 13 100 companies producing technical textiles (of the estimated 24 500 active companies) are estimated to be affected by a restriction. |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| Fluoropolymers account for the majority of the use of PFASs in technical textiles. | that function as permanent load-bearing architectural elements (i.e. tensile architecture)<br>• Non-load bearing textiles/membranes used for shading purposes, etc. in buildings or other permanent infrastructure installations<br>• Non-architectural/non-infrastructure uses requiring tensile strength (sails)<br>• Uses of PVDF in filtration and separation media for water treatment and purification<br>• Air filters for general (HVAC) ventilation<br>• Filtration and separation for production of food and beverages<br>• Disposable technical textiles for medical applications and membranes used in reuseable technical textiles for medical applications<br><br>Weak evidence that the substitution potential is high at EiF for:<br>• Yarn treatments for use in permanent load-bearing architectural elements (i.e. tensile architecture)<br>• Removable covers for industrial process equipment (insulation jacketing)<br><br>Weak evidence that the substitution potential is low at EiF for:<br>• Weaving fibres/yarns and sewing threads used for permanent load-bearing architectural elements (i.e. tensile architecture)<br>• Technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay.<br>Sufficiently strong evidence that the substitution potential is low at EiF for:<br>• Uses of PTFE in filtration and separation media for water treatment and purification<br>• High-performance applications of filtration and separation media used for air and other gases | • Total producer surplus losses as a result of business closures (in comparison to other TULAC and technical textile sub-sectors) are expected to be:<br>(i) minor in relation to outdoor technical textiles (and likely offset to some extent by gains of other companies due to a medium to high offsetting potential);<br>(ii) medium in relation to architectural membranes, other tensile fabrics and other construction applications (which are potentially offset to some extent given the low to medium offsetting potential) and potentially supplemented by some producer surplus losses in the wider supply chain (depending on the offsetting potential);<br>(iii) medium in relation to filtration and separation media (and likely offset to some extent by gains of other companies due to a medium offsetting potential) and potentially supplemented by some producer surplus losses in the wider supply chain;<br>(iv) medium in relation to removable covers for industrial process equipment (with considerable additional producer surplus losses in the wider supply chain in contrast to other sub-sectors);<br>(v) medium in relation to technical textiles for medical applications with likely some additional producer surplus losses in the wider supply chain; and<br>(vi) medium in relation to technical textiles for transport vehicles (with considerable additional producer surplus losses in the wider supply chain in contrast to other sub-sectors). |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | • Sound-permeable and vent filters for electrical and electronic equipment<br>• Oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries<br>• Media for liquid-liquid separation (at least some high-performance applications)<br>• C6 chemistry applied in reusable technical textiles for medical applications<br>• Technical textiles used for NVH insultation and ignition protection in engine bays in transport vehicles<br>As it is not possible to reliably differentiate between specific water treatment and purification processes that require the continued use of PTFE versus those that can already substitute to alternatives (i.e., current uses of PVDF), the Dossier Submitters conclude that, overall, the substitution potential for filtration and separation media for water treatment and purification is low at EiF.<br>While it is (with few exceptions) not possible to reliably differentiate between specific uses where alternatives are likely to be technically feasible and specific uses where they are not, the Dossier Submitters furthermore conclude that, apart from air filters for general (HVAC) ventilation, the substitution potential for filtration and separation media for air and other gases is low at EiF.<br>Insufficient information to conclude on the substitution potential at EiF for:<br>Ophthalmic packaging vents | • Total producer surplus losses as a result of substitution (in comparison to other TULAC and technical textile sub-sectors) are (expected to be) (i) major in relation to outdoor technical textiles, (ii) major in relation to architectural membranes, other tensile fabrics and other construction applications, (iii) minor in relation to filtration and separation media, (iv) minor in relation to removable covers for industrial process equipment, (v) major in relation to technical textiles for medical applications and (vi) minor in relation to technical textiles for transport vehicles.<br>• Consumer surplus losses resulting from price changes associated with substitution in comparison to other TULAC and technical textile sub-sectors are (expected to be) (i) minor in relation to outdoor technical textiles, (ii) minor in relation to architectural membranes, other tensile fabrics and other construction applications, (iii) very minor in relation to filtration and separation media, (iv) very minor in relation to removable covers for industrial process equipment, (v) very minor for technical textiles for medical applications and (vi) very minor for technical textiles for transport vehicles.<br>• Major welfare losses or additional costs as a result of lower functionality are expected, e.g.<br>(i) negative impacts on the service life duration of outdoor technical textiles and associated costs for, e.g. repairing seams, as well as similar impacts in |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | relation to e.g. permanent load-bearing architectural elements;<br>(ii) the absence of suitable filtration and separation media for some water treatment and purification applications (incl. wastewater treatment) and some negative impacts on e.g. filtration performance, service life duration and the energy efficiency of filtration processes, where alternatives are deemed technically feasible;<br>(iii) the absence of suitable filtration and separation media for the filtration and separation of air and other gases for many technically demanding or specialised applications, which is expected to lead to significant impacts for end users up to temporary business closures for downstream use industries; and<br>(iv) the absence of many other products used for filtration and separation purposes (including vents), reuseable medical textiles and suitable textiles for noise, vibration and harshness (NVH) insultation and ignition protection in engine bays, which could (amongst other impacts) lead to a reduction of technical standards in the industry and potential higher loss of life.<br>• Employment losses are expected, mainly in relation to the manufacture of removable covers for industrial process equipment and technical textiles for use in transport vehicles, for which the expected share of business closures is particularly high. Around 10 100 to 10 700 companies are companies estimated to produce technical textiles in relation to which a high or medium share of |

| Use sector | Alternatives | Cost impact |
|---|---|---|
| | | business closures is expected in the case of a full ban.<br>Conclusion: Given the above impacts, which include potential impacts on the health and safety of the EU population, e.g. as a result of the absence of suitable HEPA filters and an increased risk of injury in the case of a car accident, the costs of a full ban of PFAS (with an 18-month transition period) would be: Very high |
| **Broader industrial uses** | Three sub-uses have been identified within broader industrial uses: hydraulic fluids, solvents and precision cleaning, and catalysts and processing aids.<br>Insufficient information **[no evidence]** to conclude on the substitution potential of hydraulics fluids.<br>Sufficiently strong evidence to conclude that there is low substitution potential for industrial uses of PFAS in solvents and precision cleaning applications which require a combination of all or many of the properties currently provided by these substances. However, due to the limited information available on specific industrial uses of PFAS in broader industrial uses, the Dossier Submitters cannot distinguish with sufficient confidence between specific industrial uses where alternatives are currently suitable from those where they currently are not.<br>Sufficiently strong evidence to conclude that there is a low substitution potential for industrial uses of PFAS in catalysts and processing aids which require a combination of all or many of the properties currently provided by these substances. However, for ionic liquids the development of the applications is still in an early phase, making substitution possible within a shorter time period. | Alternatives are typically cheaper than PFAS used as catalysts and processing aids. Therefore, in general, such alternatives are deemed to be economically feasible when technically feasible.<br>The impacts on users depend on the ability to change production to alternatives, other products, and the share of the producers' market having the possibility to do so. Costs are expected to be major due to direct impacts such as loss of sales and R&D efforts to identify suitable alternatives<br>No information has been identified on costs on downstream users, welfare losses, or employment losses.<br>Conclusion: High costs, given that technically and economically feasible alternatives still need to be identified for most applications. |

**Table 11. RO2 - Summary table of derogations for PFAS use sectors, with substantiation for the derogation period (5 or 12 years) and with cost impacts for the 5- and/or 12-year derogation periods.**

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
|---|---|---|---|
| **TULAC (Annex E.2.2.)[38]** | | | |
| **Sector as a whole (excluding technical textiles)**<br>Fluoropolymers account for the majority of the use of PFASs in TULAC. | • Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for (i) home textiles, (ii) consumer apparel, (iii) professional apparel, (iv) leather applications, and (v) home fabric treatments<br>• In light of the sufficiently strong evidence pointing to the unavailability of alternatives at EiF, derogations are proposed for:<br>○ Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I (§5a)<br>○ Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers (§5b)<br>○ Impregnation agents for re-impregnating of articles referred to above (§5c) | Ban with a transition period of 18 months and a **12-year** derogation:<br>Based on current knowledge, PFAS are deemed to be required to achieve performance standards for many types of PPE. As no potential alternatives are identified for many types of PPE as of now, it is likely that they will not become available in the near future. Stakeholder information presented in Annex E suggests furthermore that between 1 and 3 years might be needed to complete substitution once a suitable alternative has been identified due to time requirements for product development, testing and approval in the supply chain and certification [Sufficiently strong evidence base]. | Ban with a transition period of 18 months and a 5-year derogation:<br>• The costs are expected to be close to the costs associated with RO1. The share of company closures in relation to leather applications might be lower than expected under RO1, where the share of business closures is deemed to be low to medium in light of stakeholder information suggesting that the time required for substitution might be 2-5 years. As shorter substitution times are reported in relation to some of the other sub-sectors (and due to uncertainty about the representativeness of provided estimates), no clear indication on the extent to which the substitution share would change can be provided.<br>• As costs associated with leather applications are however deemed to be minor (in comparison to other sub-sectors) even when assuming a low to medium share of business closures, the conclusion on the magnitude of costs holds. |

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[38] Note that the terms minor/medium/major used here are not the same as the qualitative cost descriptors defined in Step 5 of Table E.1 in Annex E. The use of minor/medium/major here should be read as indicative of the differences in impacts expected for the TULAC sub-sectors, respectively. The cost conclusion in line with the general qualitative cost descriptors is provided at the bottom of the text.

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | | <u>Conclusion</u>: Very high costs<br><u>Ban with a transition period of 18 months and a 12-year derogation:</u> Assuming that an alternative will be identified for PPE:<br>• <u>Producer surplus losses as a result of business closures</u> (in comparison to other TULAC sub-sectors) are expected to be minor for home textiles (and largely offset by gains of other companies due to a high offsetting potential), medium for consumer apparel (but largely offset by gains of other companies due to a high offsetting potential), minor for professional apparel and PPE, minor in relation to leather, and minor for home fabric treatments.<br>• <u>Producer surplus losses as a result of substitution</u> (in comparison to other TULAC sub-sectors) are (expected to be) medium for home textiles, major for consumer apparel, minor for professional apparel and PPE (due to companies being expected to pass on costs to customers to a large extent), minor in relation to leather, and unknown for home fabric treatments.<br>• <u>Consumer surplus losses resulting from price changes associated with substitution</u> in comparison to other TULAC sub-sectors are (expected to be) medium in relation to home textiles, major in relation to consumer apparel; minor in relation to professional apparel and PPE (due to the small volume of relevant products in comparison to other sub- |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | | | sectors and professional apparel and PPE only accounting for 2% of the total revenue of €147 billion reported for the textile and clothing industry), minor in relation to leather, and unknown in relation to home fabric treatments.<br>• Minor welfare losses or additional costs as a result of lower functionality are expected, e.g. a small reduction in water repellence (which seems however to be acceptable for customers in most cases according to stakeholder information); welfare losses and/or additional costs (such as increased cleaning and replacement costs) due to lower oil and dirt repellence, e.g. in relation to upholstery in public settings, sportswear and footwear, and in relation to leather applications; and additional costs resulting from high replacement frequencies or more frequent re-impregnation due to the lower ability of alternatives to withstand household laundering or dry cleaning.<br>• Employment losses are expected to be minor. According to information from the consultation on the Annex XV report, around 1 000 jobs are expected to be at risk in relation to the use of PFAS for textile finishes in sub-sectors for which alternatives are already known (i.e. all sectors other than professional apparel and PPE). (The financial impact for companies in these sub-sectors is estimated at around €146 million.) |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | | | <u>Conclusion:</u> Moderate costs |
| **Food contact materials and packaging (Annex E.2.3.)** | | | |
| **Sector as a whole** | • Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for (i) paper and board packaging, (ii) f-HDPE packaging, and (iii) non-stick surfaces in consumer cookware and domestic appliances.<br>• No derogation is proposed for (i) inks, lacquers and waxes used in printing on food contact materials and food packaging; and (ii) miscellaneous packaging applications. No evidence has been identified to indicate problems in substitution of these applications (weak evidence).<br>• In light of the sufficiently strong evidence pointing to the unavailability of alternatives at EiF, derogations are proposed for:<br>○ Polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) (§6a) ; and<br>○ Non-stick coatings in industrial bakeware. (§6b) | Ban with a transition period of 18 months and a **5-year** derogation:<br>Based on current knowledge, PFASs are deemed to be required to achieve product standards and acceptable production rates for most plastic films and sheet. As no potential alternatives are identified as of now that satisfy significant parts of the market, it is likely that they will not become available in the near future. Stakeholder information presented in Annex E indicates that the the industry is actively researching alternatives and suggests that an additional 5 years will be needed to complete substitution. [Sufficiently strong evidence base].<br><br>Ban with a transition period of 18 months and a **5-year** derogation:<br>Whilst alternatives are on the market for parts of the industrial bakeware sector, they are not accepted for production of all baked goods. Problems arise due to the variable nature of baked product for example with respect to fat and sugar content, cooking temperatures and times, harsh conditions within industrial bakeries with respect to temperature, cleaning regimes, etc., and high-performance standards to ensure production is not interrupted. A further complication is the need for collaboration not just between equipment manufacturers and bakers, but also with other | <u>Ban with a transition period of 18 months and a 5-year derogation:</u><br>• For the plastic film and sheet sub-sector several industry stakeholders have suggested a 5-year derogation (accepting that some have asked for longer periods). On this basis it is concluded that 5-years would give sufficient time for the R&D and necessary investments for change in the sub-sector. This would, in turn, reduce risks of business closure and impacts on consumers.<br><br><u>Ban with a transition period of 18 months and a 5-year derogation:</u><br>• For the industrial bakeware sector stakeholders have been reluctant to suggest a timeframe for restriction. However, given the potential for futher technical development of a variety of options currently under investigation and others that may arise from research to serve a broader range of products, a 5-year derogation would reduce impacts on the sub-sector leading in turn to reduced costs. Risks for consumers would also be mitigated to some extent. There would remain some risk of business closure in parts of the sector that are heavily reliant on PFASs, noting that some businesses currently work exclusively with them. |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | | stakeholders such as the recoating industry. Recoaters cannot plan for change until they know what the change will be. On the basis of growing experience with the use of alternatives and ongoing technical development it is concluded that a 5-year derogation would be sufficient for the sector. [Sufficiently strong evidence base]. | Conclusion for the sector overall:<br>Moderate costs |
| **Metal plating and manufacture of metal products (Annex E.2.4.)** [39] | | | |
| **Hard chrome plating**<br>Fluoropolymers are not used in the process of hard chrome plating and will not be affected by the derogation. | There is sufficiently strong evidence that alternatives are still being sought for hard chrome plating though there has been some success, indicating that a derogation beyond the 18-month transition period may be beneficial for the industry.<br>The following derogation is proposed:<br>• Hard chrome plating (§5d) | Sufficiently strong evidence that the time required to transition to alternatives is five years after EiF to suggest that a transition time of five years is needed after EiF for hard chrome plating. | A 5-year derogation would permit a longer period for R&D. Responses from the consultation on the Annex XV report indicated that this time frame is enough for developing an alternative for hard chrome plating. This would also limit potential impacts on consumers and the risk of job losses.<br>The number of affected companies and the complexity of the substitution process indicates that costs may still not be low.<br>Conclusion: Low to Moderate costs. |

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[39] The use of PFASs used for the production of parts for use in engines and other applications in technical compartments, etc. is covered under transport applications.
The use of PFASs used for the production of parts for use in machinery is, as other industrial applications such as sealings, covered in a separate section.
The use of PFASs used for the production of parts for military equipment is covered under applications of PFASs in the military context.
The use of PFASs used for coil coating of metals is covered under construction applications
The use of PFASs used as cover gases for use in magnesium casting is covered under fluorinated gases.
The use of PFASs used as oils and lubricants is covered under lubricants.

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| **Decorative chrome plating, chrome plating on plastics and plating with metals other than chrome**<br>Fluoropolymers are not used in the process of decorative chrome plating and chrome plating on plastics.<br>Fluoropolymers are used in plating processes with metals other than chrome. | Given sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for decorative chrome plating.<br>Given weak evidence concerning the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for chrome plating on plastics, nickel plating, aluminium anodizing, or plating with other metals. | Not applicable | Same as under RO1 |
| **Manufacture of metal products not addressed elsewhere**<br>Mainly fluoropolymers are used in manufacture of metal products. | Given sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for razor blades.<br>Given weak evidence concerning the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for coatings or solvents used in metal manufacturing. | Not applicable | Same as under RO1 |
| **Consumer mixtures and miscellaneous consumer articles (Annex E.2.5.)** | | | |
| **Sector as a whole** | Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed. | Not applicable | Same as under RO1 |
| **Cosmetics (Annex E.2.6.)** | | | |
| **Cosmetic products**<br>Some use of fluoropolymers in cosmetic products. | Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed. | Not applicable | Same as under RO1. |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| **Peptide synthesis for cosmetic applications**<br>No reported use of fluoropolymers in peptide synthesis. | Given the inconclusive evidence on the non-existence of technically and economically feasible alternatives for replacing PFAS in peptide synthesis for cosmetic applications, no derogation is proposed. | Not applicable | Same as under RO1. |
| **Ski wax (Annex E.2.7.)** | | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to ski wax is minor. | Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed. | Not applicable | Same as under RO1. |
| **Applications of fluorinated gases (Annex E.2.8.)**<br>*Note that mobile air conditioning (MAC) and transport refrigeration are covered under Transport below.* | | | |
| **Sector as a whole** | Given the sufficiently strong evidence (and in the case of sand casting weak evidence) pointing to the existence of alternatives at EiF, no derogation is proposed for:<br>• Domestic, commercial and industrial refrigeration, with the exception of some specific uses listed below<br>• Domestic, commercial and industrial air conditioning and heat pumps<br>• Heat pumps in tumble driers<br>• Propellants, with the exception of some specific uses listed below<br>• Cover gases<br>• Clean fire suppressants, with the exception of some specific uses listed below<br>• Insulating gas in electrical equipment for applications up to 145 kV<br>In light of the sufficiently strong evidence pointing to the unavailability | A ban with a transition period of 18 months and a **5-year** derogation is proposed for:<br>• Refrigerants in low temperature refrigeration below -50 °C<br>• Insulating gases in high-voltage switchgear (above 145 kV)<br>The above 5-year derogations are proposed for the following reasons:<br>In relation to refrigerants in low temperature refrigeration below –50 °C, there is sufficiently strong evidence that alternatives do not yet exist. Based on stakeholder feedback, there is, however, some potential for alternatives to be feasible for low temperature refrigeration after a 5-year derogation in addition to the transition period of 18 month.<br>In relation to insulating gases in high-voltage switchgear (above 145 kV), there is sufficiently strong evidence that alternatives are not yet on the market and that the substitution | Ban with a transition period of 18 months and a 5-year derogation for all time-limited derogations as well as two time-unlimited derogations:<br>For low temperature refrigeration below –50 °C, a 5-year derogation would permit a longer period for R&D which according to stakeholder feedback might be sufficient for identifying and implementing alternatives. A 5-year derogation would thus reduce the impacts on producers, whilst maintaining production rates and quality. It would also likely limit the impacts on end-users and avoid the adverse impacts on wider society in relation to healthcare services.<br>In relation to insulating gas in high-voltage switchgear, additional time provides manufacturers and downstream users the opportunity to substitute instead of ceasing operation thereby limiting impacts on manufactures, e.g. producer surplus |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | of suitable alternatives at EiF, derogations are proposed for:<br>• Refrigerants in low temperature refrigeration below -50 °C (§5e)<br>• Refrigerants in laboratory test and measurement equipment (§5f)<br>• Refrigerants in refrigerated centrifuges (§5g)<br>• Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives (§5h)<br>• Foam blowing agents in thermal insulation foam (§5i)<br>• Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required. The derogation does not apply to products intended for entertainment and decorative purposes for the general public (§5j)<br>• Fluorinated gases used as clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health (§5k)<br>• Preservation of cultural paper-based materials (§5l)<br>• Insulating gases in high-voltage switchgear (above 145 kV) (§5m) | potential at EiF is low. Information provided by stakeholders suggests, however, that high-voltage electricity products up to 420 kV may start to be replaced with non-PFAS alternatives by 2026. It is, however, expected that time beyond 2026 will be needed before a complete substitution to alternatives is possible. A 5-year derogation is therefore proposed.<br>A ban with a transition period of 18 months and a **12-year** derogation is proposed for:<br>• Refrigerants in laboratory test and measurement equipment<br>• Refrigerants in refrigerated centrifuges<br>• Foam blowing agents in thermal insulation foam<br>• Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required. The derogation does not apply to products intended for entertainment and decorative purposes for the public.<br>• Fluorinated gases used as clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health<br>• Preservation of cultural paper-based materials<br>The above 12-year derogations are proposed for the following reasons: | losses, and customers. Given that the industry is in the process of substituting away from PFAS, it is expected that costs would be limited if sufficient time is given for the transition, and that a 5-year derogation would be sufficient for the transition.<br>For the other uses (refrigerants in laboratory test and measurement equipment, refrigerants in refrigerated centrifuges, relevant applications at the CERN site, foam blowing agents, propellants, clean fire suppressants and the use of fluorinated gases for the preservation of cultural paper-based materials), the costs are expected to be close to the costs associated with RO1 as it is unlikely that alternatives will become available in that timeframe.<br>Building codes limiting the use of alternatives for certain HVACR-equipment are reviewed and updated regularly. It is expected that they will over time be changed through recognition of technical developments and recognition of safe operation of alternatives. The time-unlimited derogation prevents costs to manufacturers and end-users until this happens.<br>The time-unlimited derogation for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment will prevent costs related to the premature redundancy of relevant equipment. As |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | In light of the sufficiently strong evidence pointing to the unavailability of suitable drop-in alternatives, a derogation is proposed for:<br>• Refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months after EiF (§5n)<br>A potential derogation for consideration is included for:<br>• [Use of fluorinated gases at the CERN research installation] (§5o) | As no alternatives are identified as of now, it is likely that they will not become available in the near future.<br>A **potential 12-year derogation for consideration** for the use of fluorinated gases at the CERN research installation is considered given sufficiently strong evidence on the non-existence of alternatives at EiF. However, the Dossier Submitters are not able to conclude on the proportionality of this potential site-specific derogation.<br>**Time-unlimited** derogations are proposed for:<br>• Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives<br>• Refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months after EiF<br>The above time-unlimited derogations are proposed for the following reasons: Building codes limiting the use of alternatives for certain HVACR-equipment are reviewed and updated regularly. It is expected that they will over time be changed through | a result, the associated costs are deemed to be low.<br>The overall costs are therefore expected to be:<br>• Very high in relation to refrigeration (as for RO1, due to the continued non-existence of alternatives for several applications, which could lead to some impacts on healthcare services);<br>• Low in relation to air conditioning and heat pumps;<br>• Very high in relation to foam blowing agents (as for RO1);<br>• Very high in relation to propellants (as for RO1);<br>• Low in relation to cover gases (as for RO1);<br>• Very high in relation to clean fire suppressants (as for RO1);<br>• High in relation to the preservation of cultural paper-based materials (as for RO1); and<br>• Low in relation to insulating gas in electrical equipment.<br><u>Conclusion:</u><br>Overall, the costs associated with all relevant applications of fluorinated gases are still deemed to be:<br>Very high<br><u>Ban with a transition period of 18 months and a 12-year derogation for all</u> |

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
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| | | recognition of technical developments and recognition of safe operation of alternatives. The time-unlimited derogation prevents costs to manufacturers and end-users until this happens.<br>The time-unlimited derogation for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment will prevent costs related to the premature redundancy of relevant equipment. Most equipment has a typical lifetime of 15 -25 years, with some industrial equipment potentially having lifetimes up to 40 years. While the derogation is time-unlimited, it will in practice be limited by the replacement of equipment and the end of its lifetime. It will ensure that the equipment will gradually be phased out and replaced with non-PFAS equipment. | time-limited derogations (except for low temperature refrigeration and insulating gases in high-voltage switchgear) as well as two time-unlimited derogations:<br>Assuming that alternatives will be identified for the uses for which alternatives do not exist at EiF, the costs are expected to be:<br>• Low in relation to refrigeration;<br>• Low in relation to air conditioning and heat pumps;<br>• Low in relation to foam blowing agents;<br>• Low in relation to propellants;<br>• Low in relation to cover gases (as for RO1)<br>• Low in relation to clean fire suppressants;<br>• Low in relation to the preservation of cultural paper-based materials; and<br>• Low in relation to insulating gas in electrical equipment.<br>Conclusion:<br>Overall, the costs associated with all relevant applications of fluorinated gases are deemed to be:<br>Low |
| **Medical devices (Annex E.2.9.)** | | | |
| **Implantable medical devices** (including medical implants and meshes) | Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: | Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence]. | Ban with a transition period of 18 months and a 12-year derogation:<br>If feasible alternatives are identified, developed and approved, the public health concerns (and their related |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | • Implantable medical devices (including medical implants and meshes) (§6c) | Continued R&D increases the chance that alternatives for the relevant applications will be identified. | socio-economic costs) due to reduced functionality of the devices would be avoided. |
| **Wound treatment products (non-implantable/non-invasive medical devices)** | Given the weak evidence that technically and economically feasible alternatives are not available at EiF, no derogation is proposed. | | The cost impact associated with no derogation is uncertain. |
| **Tubes and catheters (invasive medical devices)** | Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for:<br>• Invasive medical devices (e.g. tubes and catheters) (§6d) | Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified. | Ban with a transition period of 18 months and a 12-year derogation:<br>If feasible alternatives are identified, developed and approved, the public health concerns (and their related socio-economic costs) due to reduced functionality of the devices would be avoided. |
| **Other coating applications (non implantable medical devices)** | Given the weak evidence that technically and economically feasible alternatives are available at EiF, no derogation is proposed. | | The cost associated with coating applications is uncertain. |
| **Sterilization gases** | Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed. | Not applicable | Same as under RO1. |
| **Vision applications (invasive medical devices)** | Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is proposed for: invasive medical devices (e.g. tubes and catheters). (§6d) | Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete, sufficiently strong evidence base. Continued R&D increases the chance that alternatives for the relevant applications will be identified. | Ban with a transition period of 18 months and a 12-year derogation:<br>If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the devices would be avoided. |
| **Packaging of medical devices** | Given the sufficiently strong evidence that technically and economically feasible alternatives are not available | Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would | Ban with a transition period of 18 months and a 12-year derogation: |

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
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| | at EiF, a derogation is proposed for the packaging for medical devices (§6e). | take more than five years to complete [sufficiently strong evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified. | If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the packaged devices would be avoided. |
| **Transport (Annex E.2.10.)** | | | |
| **Uses of fluoropolymers and perfluoropolyethers in transport vehicles[40] (excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles)**<br>Use of fluoropolymers. | Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF for at least some applications of fluorpolymers and perfluoropolyethers, and since the Dossier Submitters cannot exclude that for some of the applications where the substitution potential is low, fluoropolymers and/or perfluoropolyethers are fundamental to ensure the safety and/or the environmental performance of transport vehicles, a derogation is proposed for:<br>• Vehicle systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles)] that are subject to EU vehicle type approval, where the type approval was obtained within | Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified. | Ban with a transition period of 18 months and a 5-year derogation:<br>Same as under RO1.<br>Ban with a transition period of 18 months and a 12-year derogation:<br>Assuming that an alternative will be identified for the uses for which alternatives do not exist at EiF, the costs are expected to be lower than in RO1.<br>Conclusion: Low costs |

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[40] This includes: Foam mouldings; Tubes and hoses in combustion engine systems; Protective coatings and paints for transport vehicles; Hydrophobic coatings for windshields; Cable liners & coatings for transport vehicles, including high-voltage insulators; Anti-fouling coatings for ships; Surface coatings for exterior sensors; Anti-icing coating for helicopter rotors; Trim materials for vehicle interiors; Coating of insulation materials; Coatings to reduce fuel consumption and emissions; FEP based heat shrink sleeving; Liners for aerospace hoses; and Wrap for aluminium fan cases for jet engines.

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | 13.5 years after EiF (e.g. motor vehicles within the scope of Regulation (EU) 2018/858, (EU) 2019/2144 or Directive 2007/46/EC, agricultural and forestry vehicles with the scope of Regulation (EU) 167/2013, aircraft within the scope of Regulation (EU) 2018/1139 or (EU) 748/2012, watercraft within the scope of Directive 2013/53/EU or 2009/45/EC, and rail vehicles within the scope of Regulation (EU) 2016/797 or Directive (EU) 2016/798);<br>• Systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles)] in vehicles that are not within the scope of paragraph a, where the use of fluoropolymers or perfluoropolyethers are strictly necessary for safety or environmental performance of those vehicles until 13.5 years after EiF. e.g. braking, restraint, lighting/signalling, driver assistance systems, emission control (§6f). | | |
| **Reflective coatings for traffic signs**<br>Use of fluoropolymers. | Given no evidence on the substitution potential at EiF: no derogation is proposed. | Not applicable. | Same as under RO1. |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| **Additives to hydraulic fluids in transport vehicles**<br>No use of fluoropolymers. | Given sufficiently strong evidence that alternatives are not available at EiF, a derogation is **proposed** for:<br>- Additives to hydraulic fluids in transport vehicles (§5p). | Ban with a transition period of 18 months and a **12-year** derogation, as identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence base].<br>Continued R&D increases the chance that alternatives for the relevant applications will be identified. | Ban with a transition period of 18 months and a 5-year derogation:<br>Same as under RO1 (Very high costs).<br>Ban with a transition period of 18 months and a 12-year derogation:<br>Assuming that an alternative will be identified the costs will be lower than in RO1.<br>However, stakeholders indicate that a switch to an alternative corrosion inhibitor might lead to a need to replace the whole hydraulic fluids or even the need for a complete redesign of current aircraft hydraulic systems operation and maintenance practices. Stakeholders also expect that any alternatives would most likely have worse performance than the currently used PFAS additives, resulting in faster onset of corrosion damage in the hydraulic system of aircraft. Any reduction in performance would be associated with reductions in safety, with potential associated loss of life. This reduction in performance in itself, as well as the uncertainties related to switching from an existing system that operators have decades of experience with to a new system, will increase the frequency of controls, maintenance and repair activities among aircraft operators. This could result in disruption to air travel in general in the EEA, with fewer planes being available for service and, thus, reduced flight capacity.<br>Conclusion: Moderate costs |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| **Devices for motion control solutions**<br><br>No use of fluoropolymers. | Given no evidence on the substitution potential at EiF: no derogation is proposed. | Not applicable. | Same as under RO1. |
| **Mobile Air Conditioning (MAC) and heat pump systems**<br><br>No use of fluoropolymers. | Given the sufficiently strong evidence pointing to a low substitution potential at EiF, derogations are **proposed** for:<br>• Refrigerants in mobile air conditioning (MAC) and heat pump systems in<br>i. Light duty electrical vehicles; and<br>ii. All other vehicles (§5q)<br><br>In light of the sufficiently strong evidence pointing to the unavailability of suitable drop-in alternatives, a derogation is proposed for:<br>• Maintenance and refilling of mobile air conditioning and heat pump equipment placed on the market before the end of the 18-month general transitional period (or placed on the market on the basis of an applicable derogation) (§5n). | Ban with a transition period of 18 months and a **5-year** derogation for light duty electrical vehicles, to provide opportunity for R&D to bring the already identified alternatives to the mass market.<br><br>Ban with a transition period of 18 months and a **12-year** derogation for all other vehicles, because identification and development of alternatives would take more than five years to complete.<br><br>A **time-unlimited** derogation is proposed for:<br>• Maintenance and refilling of mobile air conditioning and heat pump equipment placed on the market before the end of the 18-month general transitional period (or placed on the market on the basis of an applicable derogation).<br><br>The time-unlimited derogation is proposed for the following reason: The derogation will prevent costs related to the premature redundancy of relevant equipment. While the derogation is time-unlimited, it will in practice be limited by the replacement of equipment and the end of its lifetime. It will ensure that the equipment will gradually be phased out and replaced with non-PFAS equipment. | Ban with a transition period of 18 months and a 5-year derogation as well as a time-unlimited derogation:<br><br>*Light duty electrical vehicles*<br>A 5-year derogation would permit a longer period for R&D which according to stakeholder feedback would be sufficient for implementing already identified alternatives. Lower producer surplus losses than under a full ban (RO1) are expected given the added time to develop alternative systems. Consumer losses might be low but ultimately depend on the extent to which manufacturers are able to pass costs onto consumers.<br><br>Conclusion: Low costs.<br><br>*All other vehicles*<br>Same as under RO1 (Very high costs).<br><br>*Existing equipment*<br>The time-unlimited derogation for maintenance and refilling of existing equipment will prevent costs related to the premature redundancy of relevant equipment. As a result, the associated costs are deemed to be low.<br><br>Ban with a transition period of 18 months and a 12-year derogation as well as a time-unlimited derogation:<br>*Light duty electrical vehicles* |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | | Same as under the 5-year derogation (Low costs).<br>*All other vehicles*<br>Assuming that an alternative will be identified the costs will be lower than in RO1. Stakeholder information submitted to the consultation on the Annex XV report indicates that it is possible for "early movers" to have alternatives on the mass market for other vehicles in 2034.<br>Conclusion: Low costs.<br>*Existing equipment*<br>The time-unlimited derogation for maintenance and refilling of existing equipment will prevent costs related to the premature redundancy of relevant equipment. As a result, the associated costs are deemed to be low. |
| **Transport refrigeration**<br>No use of fluoropolymers. | Given the sufficiently strong evidence pointing to a low substitution potential at EiF, a derogation is proposed for:<br>• Refrigerants in transport refrigeration other than in marine applications (§5r).<br>In light of the sufficiently strong evidence pointing to the unavailability of suitable drop-in alternatives, a derogation is proposed for:<br>• Maintenance and refilling of transport refrigeration equipment placed on the market before the end of the 18-month general transitional | Ban with a transition period of 18 months and a **5-year** derogation, because significant modification of vehicle/trailer design as well as new refrigeration systems are needed for refrigeration in these transport vehicles.<br>A **time-unlimited** derogation is proposed for:<br>• Maintenance and refilling of transport refrigeration equipment placed on the market before the end of the 18-month general transitional period (or placed on the market | Ban with a transition period of 18 months and a 5-year derogation as well as a time-unlimited derogation:<br>A 5-year derogation would provide opportunity for further development of systems and integration with other vehicle components for typical uses. This would have economic benefits to both producers and consumers. Costs to industry would be reduced compared to RO1 because of increased potential for developing and certifying alternatives. Consumers might also face lower costs than under RO1 and benefit from systems that are better integrated into vehicle design. |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | period (or placed on the market on the basis of an applicable derogation) (§5n). | on the basis of an applicable derogation).<br>The time-unlimited derogation is proposed for the following reason: The derogation will prevent costs related to the premature redundancy of relevant equipment. While the derogation is time-unlimited, it will in practice be limited by the replacement of equipment and the end of its lifetime. It will ensure that the equipment will gradually be phased out and replaced with non-PFAS equipment. | Conclusion: Low costs.<br>The time-unlimited derogation for maintenance and refilling of existing equipment will prevent costs related to the premature redundancy of relevant equipment. As a result, the associated costs are deemed to be low. |
| **Electronics and semiconductor (Annex E.2.11.)** | | | |
| **Sector as a whole (Electronics and semiconductors)** | Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for:<br>• Heat transfer fluids for 1-phase immersion cooling<br>Given the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a derogation is **proposed** for:<br>• Heat transfer fluids for industrial and professional use of vapor phase soldering (§6g)<br>• Wires and cables (incl. connectors) (§6h)<br>• Insulation material of electronic components (excluding wires, cables and connectors)) (§6i)<br>• Coating / film of electronic components (§5s) | Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [strong evidence base] for<br>• Heat transfer fluid for vapor phase soldering<br>• Wires and cables (incl. connectors)<br>• Insulation material of electronic components<br>• Coating and films of electronic components (Excluding displays and lenses)<br>• Printed circuit boards and antennas<br>• Photonics<br>• Anti-drip agents in plastic of electronic components<br>• Heat transfer fluids for 2-phase immersion cooling<br>• Semiconductors manufacturing | Ban with a transition period of 18 months and a 5-year derogation:<br>The costs are expected to be close to the costs associated with RO1, i.e. very high costs.<br>Ban with a transition period of 18 months and a use-specific 12-year derogation:<br>If feasible alternatives are identified, developed and approved, manufacturing in the EEA and imports from non-EEA articles can continue without supply disruptions. Accordingly, impacts resulting from the non-availability of articles would be minimized for industrial and professional users as well as consumers. Unknown, but significant costs are expected for development, qualification, certification and registration of an unknown but very high number of electronic articles and complex articles using electronics. |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | • Printed circuit boards and antennas (§5t)<br>• Photonics (§5u)<br>• Anti-drip agents in plastics of electronic components (§6j)<br>• Heat transfer fluids for 2-phase immersion cooling (§5v)<br>• Semiconductor manufacturing (§5w)<br>Given the sufficiently strong evidence pointing to a low substitution potential at EiF, a derogation is proposed for:<br>• Coating and film on displays and lenses of electronic complex objects (§5x)<br>Due to only weak evidence suggesting that technically feasible alternatives might not exist, no derogation is proposed for:<br>• Electronic components – all sub-uses except Printed circuit boards and antennas<br>• Heat transfer fluids – other applications e.g. cold plate cooling | Ban with a transition period of 18 months and a **5-year** derogation, because promising alternatives still need to be tested and implemented [strong evidence base] for<br>• Coating and films on displays and lenses of electronic complex objects | The eventual socio-economic costs would be significantly lower compared to RO1:<br>Conclusion: moderate costs. |
| **Energy sector (Annex E.2.12.)** | | | |
| **Sector as a whole** | Given that no evidence is available pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for:<br>• ETFE in enclosed trough technology (solar collectors) in the field of renewable energy<br>• Coating of wind turbines (blades and tower) | Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [strong evidence base] for<br>• Binders and electrolytes in batteries<br>• fuel cells and electrolysis technology | Ban with a transition period of 18 months and a 5-year derogation:<br>Same as under RO1, i.e. very high costs.<br>Ban with a transition period of 18 months and a 12-year derogation:<br>If feasible alternatives are identified, developed and approved, the eventual |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | Given the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a derogation is **proposed** for:<br>• Binders and electrolytes in batteries (§5y)<br>• fuel cells and electrolysers (§6k)<br>• separator coatings for batteries (§6l)<br>• PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers (§6m)<br>• Front- and backsheets of photovoltaic cells (§6n) | Ban with a transition period of 18 months and a **5-year** derogation, because promising alternatives still need to be tested and implemented [strong evidence base] for<br>• separator coatings for batteries<br>• PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers<br><br>Ban with a transition period of 18 months and a **5-year** derogation, because availability of sufficient quantities after a transition period of 18 months is highly uncertain [strong evidence base].<br>• Front- and backsheets in photovoltaic cells | socio-economic costs would be significantly lower compared to RO1:<br><br><u>Conclusion: Low to moderate costs</u> |
| **Construction products (Annex E.2.13.)** | | | |
| **Sector as a whole**<br><br>Fluoropolymers account for the majority of the use of PFASs in relation to construction products.<br><br>More specifically, fluoropolymers account for:<br>• The majority of the use of PFASs in architectural coatings and paints;<br>• The entire use of PFASs in relation to coil coating, where primarily PTFE is used;<br>• A large share of the use of PFASs as polymer additives used for fire safety purposes, for which the use | • Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed for (i) architectural coatings and paints, (ii) coil coating, (iii) film/foil for greenhouses, (iv) window frames, (v) surface protection, (vi) wetting/levelling agents, in e.g. coating, paints and adhesives and (vii) processing aids for the production of construction articles<br><br>• Due to only weak evidence suggesting that technically feasible alternatives might not exist, no derogation is proposed for (i) processing aids for production of non-PFAS polymers/plastics, (ii) | Ban with a transition period of 18 months and a **12-year** derogation:<br>Based on current knowledge, no technically feasible alternatives exist for polymer additives used for fire safety purposes. As no potential alternatives are identified as of now, it is likely that they will not become available in the near future.<br><br>Similarly, there is sufficiently strong evidence that alternatives are not yet technically advanced enough for bridge and building bearings and that at least 7 years might be needed to complete substitution once a suitable alternative has been identified due to time requirements for product development, testing and third party approval. | <u>Ban with a transition period of 18 months and a 5-year derogation:</u><br>The costs are expected to be close to the costs associated with RO1.<br><br><u>Conclusion</u>: Very high costs<br><u>Ban with a transition period of 18 months and a 12-year derogation:</u><br>Assuming that alternatives will be available for polymer additives used for fire safety purposes and bridge and building bearings:<br>• As for RO1, a ban on PFASs is estimated to impact at least ~ 10 800 – 15 900 enterprises. This quantitative estimate accounts for six of the twelve uses, due to a lack of data for the other uses. |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| of non-polymeric PFASs also plays a significant role;<br>• The entire use of PFASs in film/foil for greenhouses, where ETFE is used;<br>• The entire use of PFASs in relation to processing aids for production of non-PFAS polymers/plastics;<br>• The entire use of PFASs in relation to bridge and building bearings;<br>• The majority of the use of PFASs in relation to window frames;<br>• The entire use of PFASs in relation to plumbing applications;<br>• A share of the use of PFASs in relation to surface protection, for which both fluoropolymers and side-chain fluorinated polymers are used (but the distribution is unclear);<br>• None of the use of PFASs as processing aids for the production of construction articles, for which solely non-polymeric PFASs are used; and<br>• None of the use of PFASs in relation to window film manufacturing, for which only non-polymeric PFASs are used.<br><br>In relation to wetting/levelling agents, primarily non-polymeric PFASs are used. | plumbing applications and (iii) window film manufacturing<br><br>• In light of the sufficiently strong evidence pointing to the unavailability of alternatives at EiF, derogations are proposed for:<br>○ Polymer additives used for fire safety purposes (§5z)<br>○ Bridge and building bearings (§6o) | | • Producer surplus losses: A considerable volume of products is expected to be affected by a restriction per year. This includes ~ 123 000 - 148 000 tonnes of architectural coatings and paints, ~ 8 400 – 16 800 tonnes in relation to film/foil for greenhouses, ~ 4 900 – 9 700 tonnes of bridge and building bearings, ~ 2.4 – 4.8 million window frames and ~ 24 700 – 37 000 tonnes of window films. No information on relevant volumes is available for the other seven uses. If all companies ceased the manufacture of products, this would result in total annual producer surplus losses of at least ~ €159-245 million. This quantitative estimate accounts for six of the twelve uses, due to a lack of data for the other uses. Polymer additives used for fire safety purposes, for which no technically alternatives exist at EiF, are not accounted for in this estimate. Assuming that an alternative will be identified for polymer additives and bridge and building bearings, the producer surplus losses will be significantly lower than this worst-case estimate as substitution is the most likely behavioural reaction for all uses. While substitution might still lead to producer surplus losses, e.g. due to the internalization of capital costs and/or increased operating costs associated with the transition, those are deemed to be significantly lower |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | | than producer surplus losses resulting from business closures.<br>• Consumer surplus losses and other impacts on end-users: The implications for downstream users are expected to include (i) some reduction in the lifetime of architectural coatings and paints, coil coating under harsh environmental conditions, film/foil for greenhouses, window frames, products used for plumbing application, adhesives using wetting/levelling agents, and processing aids for production of non-PFAS polymers/plastics, which will lead to additional costs for repainting/re-sheeting/more frequent replacement; (ii) some reduction of the resistance against scratches in relation to coil coating; (iii) potentially a certain, but largely acceptable, decrease in fire resistance, in relation to film/foil for greenhouses (for the alternatives PE and PP) and (iv) potentially slight differences in oil/soil repellence in relation to surface protection.<br>• Other impacts: If all companies ceased operation, this would lead to estimated employment losses in the range of<br>106 000 to 171 000 jobs, leading to social costs of between €10.5 billion and €16.9 billion. This quantitative estimate accounts for six of the twelve uses, due to a lack of data for the other uses, and is therefore an underestimate. Polymer additives used for fire safety purposes, for |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | | which no technically alternatives exist at EiF, are not accounted for in this estimate. Assuming that an alternative will be identified for these polymer additives and bridge and building bearings, employment losses are deemed to be significantly lower than this worst-case estimate as substitution is the most likely behavioural reaction for all uses. Some business closures might still occur as some companies might not consider it financially viable for them to invest in substitution.<br>Conclusion: Moderate costs |
| **Lubricants (Annex E.2.14.)** | | | |
| **Sector as a whole** | Given the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a derogation is **proposed** for:<br>• Industrial and professional uses of lubricants or lubricant additives (§5aa) | Ban with a transition period of 18 months and a **12-year** derogation as no alternatives are identified for industrial and professional uses, specifically uses under harsh conditions, it is unlikely that they will become available in the near future i.e., within a five year period. | Ban with a transition period of 18 months and a 5-year derogation:<br>Same as under RO1<br>Ban with a transition period of 18 months and a 12-year derogation:<br>The losses of functionality identified under RO1 are likely to be avoided, while costs related to reformulation and development will be spread out over a longer period of time. Nevertheless, there are large number of downstream users and end products will be affected in complex supply chains.<br>Conclusion:<br>Overall, the costs associated with all relevant industrial and professional applications are deemed to be: Moderate |
| **Petroleum and mining (Annex E.2.15.)** | | | |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| **Tracers**<br>No reported use of fluoropolymers in tracers. | Given the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives in sufficient numbers at EiF, a derogation is proposed for:<br>• Gas and oil tracers (§5bb)<br>For water tracers, given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed. | Ban with a transition period of 18 months and a **12-year** derogation for **gas and oil tracers**, because extended time will enable further research and development to identify alternatives.<br>Technically feasible alternatives in sufficient numbers have not been identified despite substantial research activities over several decades into alternatives to PFAS in gas and oil tracers. Therefore, the Dossier Submitters' conclusion is that there is sufficiently strong evidence that technically and economically feasible alternatives will not be generally available in sufficient numbers in the short term and that the substitution potential will be low. | Ban with a transition period of 18 months and a 5-year derogation:<br>Same as under RO1<br>Ban with a transition period of 18 months and a 12-year derogation:<br>The losses of functionality identified under RO1 are likely to be avoided. |
| **Anti-foaming agents**<br>No reported use of fluoropolymers in anti-foaming agents. | • Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed. | Not applicable. | Same as under RO1. |
| **Printing applications (Annex E.2.16.)** | | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to printing applications is significant. | • Given the only weak evidence pointing to a low substitution potential at EiF for (i) pigments and colourants and (ii) PTFE powders, no derogation is proposed for these uses<br>• Similarly, no derogation is proposed for (i) printing plates (offset and letterpress printing) and (ii) rollers and (iii) surfactants used in printing due to the unclear substitution potential<br>• For PTFE wax, no derogation is proposed as there is sufficiently | Ban with a transition period of 18 months and a **12-year** derogation as well as **time-unlimited derogations** for two consumables (toners and latex printing inks) to allow the use in existing equipment:<br>Based on current knowledge, drop-in alternatives do not exist for toners used in printers that are already in use, while adjustments, e.g. to printer software, to enable the use of alternatives seem to be possible for new printers. Based on stakeholder | Ban with a transition period of 18 months and 5-year derogations as well as the time-unlimited derogations:<br>The costs are expected to be close to the costs associated with RO1.<br>Conclusion: High costs<br>Ban with a transition period of 18 months and 12-year derogations as well as the time-unlimited derogations:<br>Assuming that alternatives are available for applications with weak evidence on or an unknown substitution |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | strong evidence pointing to a high substitution potential<br>• Given the sufficiently strong evidence pointing to a low substitution potential at EiF, derogations are proposed for:<br>(i) toners (§5cc)<br>(ii) latex printing inks (§5dd)<br>(iii) electrophotographic press units (§5ee)<br>(iv) kinetic printing components (§5ff)<br>(v) photosensitive materials (§5gg)<br>• Given sufficiently strong evidence on the incompatibility of alternative-based consumables with existing equipment, derogations are also proposed for two consumables with a view of avoiding the early redundancy of equipment, i.e.:<br>i) Toners for use in existing equipment put on the market before the end of the derogation period for toners (§5hh); and<br>ii) Latex printing inks for use in existing equipment put on the market before the end of the derogation for latex printing inks (§5ii) | information, between 9-12 years are estimated to be required to develop the alternative for use in toners and the new product, i.e. a generation of printers adapted to the alternative toner. For printers that are already in use, PFAS-based toners are reported to be required for between 5-7 more years to avoid the early redundancy of this equipment. [Sufficiently strong evidence base]<br><br>Similarly, between 9-12 years are estimated to be required to develop alternatives for use in electrophotographic press units [Sufficiently strong evidence base].<br><br>For latex printing inks, kinetict printing components and photosensitive materials, there is sufficiently strong evidence that alternatives do not exist. As no potential alternatives are identified as of now, it is likl that they will not become available in the near future. Based on past experience with substitution in relation to photosensitive materials, it might take around 10 years to develop and commercialise alternatives. Stakeholder information presented in Annex E furthermore suggests that PFAS-containing latex printing inks are required for up to 7 more years for printers that are already in use to avoid the early redundance of this equipment.<br><br>As printing equipment put on the market after 13.5 years after EiF would | potential, and alternatives for other consumables and permanent parts (incl. compatible equipment) will be developed, the following impacts are expected:<br>• In relation to PTFE wax, this restriction option would have minimal impact as compatible drop-in alternatives for waxes exist.<br>• This restriction option would allow time for developing alternative toners, latex printing inks, eletrophotographic press units, kinetic printing components and photosensitive materials that are compatible with existing equipment. It will also enable the use of existing equipment until the end of its service life and thereby avoid the early obsolescence of equipment.<br><br>As such, additional costs for replacing printers before the end of their expected life time will be avoided.<br><br>According to information provided by stakeholders for a select group of sub-uses, the cost of substitution could vary between €10-100 million per sub-use. Extrapolating the cost estimates provided by stakeholders (assuming even distribution) across each sub-use and assuming a scenario in which substitution is a feasible option in relation to all sub-uses results in a one-off cost of between €0.11–1.1 billion.<br><br>Conclusion: Moderate costs, due to the high complexity of substitution which involves identifying and/or developing |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | | be adapted to the new (PFAS-free) generation of toners and inks rather than PFAS-based consumables, no demand for PFAS-based consumables by owners of newly purchased equipment is expected. | alternatives for several consumables and permanent parts as well as developing equipment that is compatible with all of those |
| **Sealing applications (Annex E.2.17.)** | | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to sealing applications is significant. | Given the sufficiently strong evidence pointing to a low substitution potential at EiF for sealing applications, derogations are proposed for:<br>• Sealing applications in industrial uses until 13.5 years after EIF (§6p) | Ban with a transition period of 18 months and a **12-year** derogation<br>Based on current knowledge, suitable alternatives do not exist for sealing applications where a combination of all or many of the properties of fluoropolymers and perfluoropolyethers are required to ensure compliance with applicable performance and safety standards. Based on stakeholder information, at least 10 years are estimated to be required to develop suitable alternatives for use in these sealing applications.<br>It is furthermore concluded that there are indications that alternatives are technical feasible for sealing applications in industrial uses where a combination of only some of the properties provided by fluoropolymers and perfluoropolyethers are required to ensure compliance with applicable performance standards [weak evidence].<br>However, the Dossier Submitters cannot distinguish with sufficient confidence between specific sealing applications in industrial uses where alternatives are currently technically feasible from | Ban with a transition period of 18 months and 5-year derogations:<br>The costs are expected to be close to the costs associated with RO1.<br>Conclusion: Very high costs<br>Ban with a transition period of 18 months and 12-year derogations:<br>Assuming that suitable alternatives will be identified for the uses for which alternatives do not exist at EiF, the costs are expected to be:<br>The economic impacts would arise due to identification of alternatives and costs are expected to be lower than for RO1<br>The impacts on certain downstream users are expected to be lower compared to RO1. However, the magnitude is expected to be major since several market sectors would be affected and the substitution process is expected to be complicated.<br>Increased costs due to identification of alternatives are expected to be transferred to consumers.<br>Overall, the costs associated with all relevant applications are deemed to be: |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | | industrial uses where they currently are not.<br>Performance losses associated with the use of a alternatives do not necessarily mean that they are concluded to not be technically feasible. However, the Dossier Submitters cannot identify with sufficient confidence those specific applications where alternatives are considered technically feasible despite certain performance losses.<br>There is insufficient information to conclude on the technical feasibility of alternatives in professional and consumer uses of sealing applications. | **MODERATE** |
| **Machinery applications (Annex E.2.18.)** | | | |
| **Sector as a whole**<br>Use of fluoropolymers in relation to machinery applications is significant. | Given the sufficiently strong evidence pointing to a low substitution potential at EiF for Machinery applications, derogations are proposed for:<br>Machinery applications in industrial uses until 13.5 years after EIF (§6q) | Ban with a transition period of 18 months and a **12-year** derogation<br>Based on current knowledge, suitable alternatives do not exist for machinery applications where a combination of all or many of the properties of fluoropolymers and perfluoropolyethers are required to ensure compliance with applicable performance and safety standards. Based on stakeholder information, at least 10 years are estimated to be required to develop suitable alternatives for use in these machinery applications.<br>It is furthermore concluded that there are indications that alternatives are technical feasible for machinery | Ban with a transition period of 18 months and 5-year derogations:<br>The costs are expected to be close to the costs associated with RO1.<br>Conclusion: Very high costs<br>Ban with a transition period of 18 months and 12-year derogations:<br>Assuming that suitable alternatives will be identified for the uses for which alternatives do not exist at EiF, the costs are expected to be:<br>The economic impacts would arise due to identification of alternatives and costs are expected to be lower than for RO1. |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | applications in industrial uses where a combination of only some of the properties provided by fluoropolymers and perfluoropolyethers are required to ensure compliance with applicable performance standards [weak evidence].<br>However, the Dossier Submitters cannot distinguish with sufficient confidence between specific machinery applications in industrial uses where alternatives are currently technically feasible from industrial uses where they currently are not.<br>Performance losses associated with the use of an alternative do not necessarily mean that they are concluded to not be technically feasible. However, the Dossier Submitters cannot identify with sufficient confidence those specific applications where alternatives are considered technically feasible despite certain performance losses.<br>There is insufficient information to conclude on the technical feasibility of alternatives in professional and consumer uses of machinery applications. | The impacts on certain downstream users are expected to be lower compared to RO1. However, the magnitude is expected to be major since several market sectors would be affected and the substitution process is expected to be complicated.<br>Overall, the costs associated with all relevant applications are deemed to be:<br>**MODERATE** |
| **Other medical applications (Annex E.2.19.)** | | | |
| **Fluorinated gases as propellants in pressurized metered-dose inhalers (pMDIs)**<br>No use of fluoropolymers. | Given the low substitution potential at EiF a derogation is proposed for:<br>Propellants in pressurized metered-dose inhalers (pMDIs) (§5kk). | Ban with a transition period of 18 months and a **5-year** derogation.<br>Given the progress of the transition process, and the related experience on the required timeframe for the transition, and in the absence of well- | <u>Ban with a transition period of 18 months and 5-year derogations:</u><br>Stakeholders estimates the total cost of transition from the currently used propellants to either or both of the new propellants (HFC-152a, HFO-1234ze) to be €3 to 5 billion. In the light of the |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
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| | | substantiated indications by stakeholders suggesting the opposite, the Dossier Submitters conclude that there is no evidence suggesting that the substitution potential would remain low 6.5 years after EiF. | phase-out requirement in the F-gas regulation a transition from the currently used propellants will sooner or later need to happen regardless of a PFAS restriction. In the F-gas regulation quota allocation and trading scheme new quotas will be supplied to the market until 2049, which means that the transition away from the currently used propellants in theory could go on until then. A PFAS restriction would however lead to a faster transition and thus that the associated transitional costs would have to be paid sooner. A longer transition period also opens the possibilities for development of new alternatives associated with lower transitional costs.<br>Once a transition is completed, the changes operating costs related to the non-PFAS HFC-152a likely to be small in comparison with the PFAS HFO-1234ze. If the price per unit of $CO_2$-equivalent in the F-gas regulation quota allocation and trading system is similar to the current price level for $CO_2$ permits in the ETS, the operating costs are likely to be substantially lower for HFC-152a compared to the PFAS propellants (HFC-134a and HFC-227ea) that are currently in use.<br>Since there is no evidence that the substitution potential will be low, the implications for public health that were indicated for RO1 are not expected after the end of the derogation period. |

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
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| | | | The level of complexity and scale of the transition process indicates that the costs would be:<br>**MODERATE**. |
| **Semifluorinated alkanes (SFAs) as excipients in medicinal products for ophthalmic and dermatological therapies**<br>No use of fluoropolymers. | Given the low substitution potential at EiF a derogation is proposed for:<br>Excipients in medicinal products for ophthalmic and dermatological therapies (§5jj). | Ban with a transition period of 18 months and a **12-year** derogation.<br>Given that no technically feasible alternatives have been identified, the Dossier Submitters conclude that there is sufficiently strong evidence that the substitution potential will remain low 6.5 years after EiF. Therefore a 12-year derogation is proposed. | Ban with a transition period of 18 months and 5-year derogations:<br>Since there is sufficiently strong evidence that the substitution potential will be low, the costs are expected to be similar to RO1, i.e.:<br>**HIGH** or **VERY HIGH**<br>Ban with a transition period of 18 months and 12-year derogations:<br>If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality would be avoided. There would however be some costs related to the transition. There is however no information indicating that the substitution process would be very complex. In conclusion, if feasible alternatives are identified, the costs are expected to be:<br>**LOW** |
| **PFAS-coating in release liners and backing film in transdermal patches**<br>Fluoropolymer use. | Given the low substitution potential at EiF a derogation is proposed for:<br>Coatings in release liners and backing film in transdermal patches (§6r). | Ban with a transition period of 18 months and a **12-year** derogation.<br>Given that no technically feasible alternatives have been identified, the Dossier Submitters conclude that there is sufficiently strong evidence that the substitution potential will remain low | Ban with a transition period of 18 months and 5-year derogations:<br>Since there is sufficiently strong evidence that the substitution potential will be low, the costs are expected to be similar to RO1, i.e.:<br>**HIGH** or **VERY HIGH** |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | 6.5 years after EiF. Therefore a 12-year derogation is proposed. | <u>Ban with a transition period of 18 months and 12-year derogations:</u><br>If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality would be avoided. There would however be some costs related to the transition. There is however no information indicating that the substitution process would be very complex. In conclusion, if feasible alternatives are identified, the costs are expected to be:<br>**LOW** |
| **Fluoropolymers in blisters for solid oral dose formulations**<br>Fluoropolymer use. | Given the low substitution potential at EiF a derogation is proposed for:<br>Blisters for solid oral dose formulations (§6s). | Ban with a transition period of 18 months and a **5-year** derogation.<br>Given the availability of a technically and economically feasible alternative, and in the absence of well-substantiated indications by stakeholders suggesting the opposite, the Dossier Submitters conclude that there is no evidence that the substitution potential would remain low 6.5 years after EiF. | <u>Ban with a transition period of 18 months and 5-year derogations:</u><br>Stakeholders claim that the total cost per drug and per dosage will be around €3 million. Multiplied by the number of products the total costs are estimated to be €1.9 billion.<br>The Dossier Submitters note this cost estimate, but have not been able to verify its credibility. The Dossier Submitters also note that the estimates do not seem to take into account that re-investments in the existing stock of PCTFE blister machinery will also be needed eventually.<br>Since there is no evidence that the substitution potential will be low, the implications for public health that were indicated for RO1 are not expected after the end of the derogation period. |

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
|---|---|---|---|
| | | | The level of complexity and scale of the transition process indicates that the costs would be:<br>**MODERATE** |
| **Fluoropolymer-coated rubber stoppers in vials/flasks for injectable medicinal products**<br>Fluoropolymer use. | Given the low substitution potential at EiF a derogation is proposed for:<br>Coated rubber stoppers in vials/flasks for injectable medicinal products (§6t). | Ban with a transition period of 18 months and a **12-year** derogation.<br>Given that no technically feasible alternatives have been identified for some of the applications in this area of use, the Dossier Submitters conclude that there is sufficiently strong evidence that the substitution potential will remain low for at least some applications in this area of use 6.5 years after EiF. Therefore a 12-year derogation is proposed. | <u>Ban with a transition period of 18 months and 5-year derogations:</u><br>Since there is sufficiently strong evidence that the substitution potential will be low for at least for some of the applications in this area of use, the costs are expected to be similar to RO1, i.e.:<br>**HIGH** or **VERY HIGH**<br><u>Ban with a transition period of 18 months and 12-year derogations:</u><br>If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality would be avoided. There would however be some costs related to the transition. There is however no information indicating that the substitution process would be very complex. In conclusion, if feasible alternatives are identified, the costs are expected to be:<br>**LOW** |
| **Fluoropolymer-coated packaging of transdermal patches**<br>Fluoropolymer use. | Given the uncertain substitution potential at EiF no derogation is proposed for:<br>Fluoropolymer-coated packaging of transdermal patches. | Not applicable. | Same as under RO1. |
| **Fluorinated HDPE packaging** | Given the high substitution potential at EiF no derogation is proposed for: | Not applicable. | Same as under RO1. |

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
|---|---|---|---|
| No use of fluoropolymers. | Fluorinated HDPE packaging. | | |
| **Fluoropolymer-coated canisters in pressurized metered-dose inhalers**<br>Fluoropolymer use. | Given the low substitution potential at EiF a derogation is proposed for:<br>Coated canisters in pressurized metered-dose inhalers (§6u). | Ban with a transition period of 18 months and a **12-year** derogation.<br>Given that no technically feasible alternatives have been identified, the Dossier Submitters conclude that there is sufficiently strong evidence that the substitution potential will remain low 6.5 years after EiF. Therefore a 12-year derogation is proposed. | <u>Ban with a transition period of 18 months and 5-year derogations:</u><br>Since there is sufficiently strong evidence that the substitution potential will be low, the costs are expected to be similar to RO1, i.e.:<br>**VERY HIGH**<br><u>Ban with a transition period of 18 months and 12-year derogations:</u><br>If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality would be avoided. There would however be some costs related to the transition. There is however no information indicating that the substitution process would be very complex. In conclusion, if feasible alternatives are identified, the costs are expected to be:<br>**LOW** |
| **Fluoropolymer-coated plungers in pre-filled syringes**<br>Fluoropolymer use. | Given the low substitution potential at EiF a derogation is proposed for:<br>Coated plungers in pre-filled syringes (§6v). | Ban with a transition period of 18 months and a **12-year** derogation.<br>Given that no technically feasible alternatives have been identified for some of the applications in this area of use, the Dossier Submitters conclude that there is sufficiently strong evidence that the substitution potential will remain low for at least some applications in this area of use 6.5 years after EiF. Therefore a 12-year derogation is proposed. | <u>Ban with a transition period of 18 months and 5-year derogations:</u><br>Since there is sufficiently strong evidence that the substitution potential will be low for at least for some of the applications in this area of use, the costs are expected to be similar to RO1, i.e.:<br>**HIGH** or **VERY HIGH**<br><u>Ban with a transition period of 18 months and 12-year derogations:</u><br>If feasible alternatives are identified, developed and approved, the eventual |

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
|---|---|---|---|
| | | | socio-economic costs due to reduced functionality would be avoided. There would however be some costs related to the transition. There is however no information indicating that the substitution process would be very complex. In conclusion, if feasible alternatives are identified, the costs are expected to be:<br>**LOW** |
| **PFAS in pre-filled injection pens & autoinjectors**<br>Fluoropolymer use. | Given the low substitution potential at EiF a derogation is proposed for:<br>Pre-filled injection pens & autoinjectors (§6w). | Ban with a transition period of 18 months and a **12-year** derogation.<br>Given that no technically feasible alternatives have been identified for some of the applications in this area of use, the Dossier Submitters conclude that there is sufficiently strong evidence that the substitution potential will remain low for at least some applications in this area of use 6.5 years after EiF. Therefore a 12-year derogation is proposed. | Ban with a transition period of 18 months and 5-year derogations:<br>Since there is sufficiently strong evidence that the substitution potential will be low for at least for some of the applications in this area of use, the costs are expected to be similar to RO1, i.e.:<br>**HIGH** or **VERY HIGH**<br>Ban with a transition period of 18 months and 12-year derogations:<br>If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality would be avoided. There would however be some costs related to the transition. There is however no information indicating that the substitution process would be very complex. In conclusion, if feasible alternatives are identified, the costs are expected to be:<br>**LOW** |
| **Military applications (Annex E.2.20.)** | | | |
| **Sector as a whole** | | Ban with a transition period of 18 months and a **12-year** derogation. | Ban with a transition period of 18 months and a 5-year derogation: |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| Use of fluropolymers (fluoroelastomers) | Given the low substitution potential at EiF a derogation is proposed for:<br>All uses of PFAS in military applications (§5ll). | Given that qualification and introduction of an alternative has sufficiently strong evidence for requiring 10 to 15 years for introduction and the low substitution potential at EiF a derogation of 12 years is proposed. | The substitution potential remains unchanged for all uses from their initial estimation under RO1. Costs are therefore estimated at:<br>**VERY HIGH**<br><u>Ban with a transition period of 18 months and a 12-year derogation:</u> With a derogation of 12-years substitution potential remains uncertain for mining and blasting, transport and professional and consumer uses. The costs can therefore still not be estimated under RO2 with a 12-year derogation.<br>The 12-year derogation is expected to be sufficient for some applications of military explosives to substitute with feasible alternatives. This is expected to reduce the cost impacts from RO1 however substitution costs may still prove significant due to the assumed complexity of the supply chain, inferred from military applications. Costs for RO2 with a 12-year derogation are expected to be:<br>**MODERATE** |
| **Explosives (Annex E.2.21.)** | | | |
| **Sector as a whole**<br>Use of fluropolymers (fluoroelastomers) | Given the weak data available suggesting a low substitution potential at EiF, no derogation is proposed for PFAS used in explosives for mining and blasting, transport and professional and consumer uses. | Ban with a transition period of 18 months and a **12-year** derogation.<br>Given that qualification and introduction of an alternative has sufficiently strong evidence for requiring 10 to 15 years for introduction and the low substitution | <u>Ban with a transition period of 18 months and a 5-year derogation:</u> The substitution potential remains unchanged for all uses from their initial estimation under RO1. Costs are therefore estimated at:<br>**VERY HIGH** |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | Given the low substitution potential at EiF a derogation is proposed for:<br>All uses of PFAS for explosives in military applications (§6x). | potential at EiF a derogation of 12 years is proposed. | Ban with a transition period of 18 months and a 12-year derogation:<br>With a derogation of 12-years substitution potential remains uncertain for mining and blasting, transport and professional and consumer uses. The costs can therefore still not be estimated under RO2 with a 12-year derogation.<br>The 12-year derogation is expected to be sufficient for some applications of military explosives to substitute with feasible alternatives. This is expected to reduce the cost impacts from RO1 however substitution costs may still prove significant due to the assumed complexity of the supply chain, inferred from military applications. Costs for RO2 with a 12-year derogation are expected to be:<br>**MODERATE** |
| **Technical textiles (Annex E.2.22.)** [41] | | | |
| **Sector as a whole**<br>Fluoropolymers account for the majority of the use of PFASs in technical textiles. | Given sufficiently strong evidence pointing to a high substitution potential at EiF, no derogation is proposed for:<br>- Outdoor technical textiles | A ban with a transition period of 18 months and a **5-year** derogation is proposed for the following uses:<br>- Industrial use of fluoropolymers in filtration and separation media for | Ban with a transition period of 18 months and an assumed 5-year derogation period for all considered derogations: |

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[41] Note that the terms minor/medium/major used here are not the same as the qualitative cost descriptors defined in Step 5 of Table E.1 in Annex E. The use of minor/medium/major here should be read as indicative of the differences in impacts expected for the TULAC and technical textile sub-sectors, respectively. The cost conclusion in line with the general qualitative cost descriptors is provided at the bottom of the text.

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | • Non-load bearing textiles/membranes used for shading purposes, etc. in buildings or other permanent infrastructure installations<br>• Non-architectural/non-infrastructure uses requiring tensile strength (sails)<br>• Air filters for general (HVAC) ventilation<br>• Filtration and separation for production of food and beverages<br>• Disposable technical textiles for medical applications and membranes used in reuseable technical textiles for medical applications<br>Given sufficiently strong evidence pointing to a high substitution potential at EiF for textiles/membranes and comparable non-textile structures and weak evidence pointing to a high substitution potential in relation to yarn treatments and a low substitution potential for weaving fibres/yarns and sewing threads, no derogation is proposed for:<br>• Textiles/membranes and comparable non-textile structures that function as permanent load-bearing architectural elements (i.e. tensile architecture), including yarn treatments and sewing threads | water treatment and purification; and<br>• Sound-permeable and vent filters for electrical and electronic equipment.<br>For those uses, there is only weak evidence that substitution activities would take longer than 6.5 years after EiF and that the substitution potential would remain low. For filtration and separation media for water treatment and purification, further R&D and performance testing is needed before PEEK can be considered as technically feasible. As PEEK would likely be used for the treatment of wastewaters with challenging physico-chemical properties, rather than for the treatment of drinking water, regulatory approval could likely be achieved relatively quickly. Certification requirements, if any, would likely not take longer than several months to several years (i.e., 1-3 years).<br>Similarly, a ban with a transition period of 18 months and a **5-year** derogation is proposed for:<br>• Technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay<br>For this use, the Dossier Submitters consider that there is only weak | Overall, the costs are expected to be close to the costs associated with RO1:<br>• The number of companies producing filtration and separation media that would close business is expected to be lower than for RO1 given that producers of (i) filtration and separation media for water treatment and purification and (ii) sound-permeable and vent filters for electrical and electronic equipment might be able to substitute in the given timeframe. If trials and approval processes for alternatives for filtration and separation media for water treatment and purification that are in the R&D stage are successful, substitution will be encouraged by the high margins and low price elasticity of demand allowing affected companies to pass on substitution costs to their customers. The same applies to producers of sound-permeable and vent filters. Nevertheless, for many producers of filtration and separation media, such as producers of filtration and separation media for air and other gases and oxygen-permeable membranes, closure of business remains the most likely reaction. As such, the expected share of business closures in relation to filtration and |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | Due to weak evidence pointing to a high substitution potential at EiF, no derogation is proposed for:<br>• Removable covers for industrial process equipment (insulation jacketing)<br>Given insufficient information to conclude on the substitution potential at EiF, no derogation is furthermore proposed for:<br>• Ophthalmic packaging vents<br>In light of sufficiently strong evidence pointing to a low substitution potential at EiF, <u>derogations are proposed</u> for:<br>• Sound-permeable and vent filters for electrical and electronic equipment (§5nn)<br>• Oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries (§5oo)<br>• Industrial use as media in liquid-liquid separation (§5pp)<br>• Woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795 (with the scope of the derogation also applying to impregnation agents, | evidence that there is a lack of alternatives and that the substitution potential will be low at EiF. However, the Dossier Submitters acknowledge that substitution may require some time to meet type approval requirements. This should be possible within 6.5 years.<br>A **12-year** derogation (with a transition period of 18 months) is proposed for:<br>• HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases, excluding general (HVAC) ventilation<br>• Oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries<br>• Industrial use as media in liquid-liquid separation<br>• Woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795 (with the scope of the derogation also applying to impregnation agents, and associated processes, used for re-impregnating technical textiles for | separation media is still deemed to be ‘medium’ (as for RO1).<br>• In relation to technical textiles for use in transport vehicles, it is expected that substitution to PFAS-free alternatives should be possible within 6.5 years for textiles used for noise, vibration and harshness (NVH) insulation in compartments other than the engine bay. Companies producing such textiles are however not expected to be able to supply PFAS-free technical textiles for NVH insulation and ignition protection in the engine bay in that timeframe. As such, companies are still expected to not be able to market products for a significant share of their product portfolio. Their behavioural reaction is therefore not expected to change. The share of business closures among producers of technical textiles for use in transport vehicles is therefore expected to be ‘high’ (as for RO1).<br>• Equally, the most likely behavioural reaction is not deemed to change for all other affected producers.<br><u>Conclusion</u>: Very high costs<br><u>Ban with a transition period of 18 months and a 12-year derogation period for most derogated uses, except</u> |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | and associated processes, used for re-impregnating technical textiles for medical applications) (§5ss and 5tt)<br>• Technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection (§5qq)<br><br>In light of the inability to reliably differentiate between applications for which alternatives are feasible and those for which they are not (and the resulting conclusion that, overall, the substitution potential is low at EiF), a derogation is proposed for:<br>• Industrial use of fluoropolymers in filtration and separation media for water treatment and purification[42] (§6y)<br>• HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases, excluding general (HVAC) | medical applications)<br>• Technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection<br><br>This length of the derogation is proposed in light of sufficiently strong evidence that suitable alternatives are not available at EiF and that the substitution potential will remain low 6.5 years after EiF. Required research & development activities and, where applicable, regulatory approval process are expected to require some time.[43] | for the three uses for which a derogation of 5-years has been proposed in line with the criteria for derogations:<br>• If alternatives are identified, substitution will for filtration and separation media and technical textiles for transport vehicles be further encouraged by the high margins and low price elasticity of demand allowing affected companies to pass on substitution costs to their customers.<br>• For producers of technical textiles for medical applications, substitution is not encouraged in the same way given the expected need to partially internalize costs. Nevertheless, substitution is deemed to be a promising endeavour given the increased demand in the EU for reuseable materials (in line with environmental goals) and the lower level of comfort associated with PFAS-free disposal medical textiles that are currently on the market. As |

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[42] Filtration and separation media for 'water treatment and purification' include media used for drinking water treatment as well as the production of various grades of purified water, including ultrapure water, used for various industrial processes. It also includes filtration and separation media used for wastewater treatment.

[43] In relation to reusable technical textiles for medical applications, it is for example expected that the complete process from identification of an alternative to approved product takes at least 5-10 years, if alternatives are identified at all.

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
|  | ventilation (§5mm)<br>In addition, there is only weak evidence that that the substitution potential will be low at EiF for:<br>• Technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay (§5rr)<br>However, the Dossier Submitters acknowledge that substitution of PFAS for such parts may require some time to meet type approval requirements. A <u>derogation is therefore proposed</u>. |  | such, new PFAS-free reusable products of good quality are expected to have a significant market potential.<br>Assuming that alternatives will be identified for all applications:<br>• <u>Total producer surplus losses as a result of business closures</u> (in comparison to other TULAC and technical textile sub-sectors) are expected to be:<br>(i) minor in relation to outdoor technical textiles (and likely offset to some extent by gains of other companies due to a medium to high offsetting potential);<br>(ii) medium in relation to architectural membranes, other tensile fabrics and other construction applications (which are potentially offset to some extent given the low to medium offsetting potential) and potentially supplemented by some producer surplus losses in the wider supply chain (depending on the offsetting potential);<br>(iii) minor in relation to filtration and separation media;<br>(iv) medium in relation to removable covers for industrial process equipment (with considerable additional producer surplus losses in |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | | the wider supply chain in contrast to other sub-sectors);<br>(v) minor in relation to technical textiles for medical applications; and<br>(vi) minor in relation to technical textiles for transport vehicles.<br>• Total producer surplus losses as a result of substitution (in comparison to other TULAC and technical textile sub-sectors) are (expected to be) (i) major in relation to outdoor technical textiles (as for RO1), (ii) major in relation to architectural membranes, other tensile fabrics and other construction applications (as for RO1), (iii) minor in relation to filtration and separation media (given the high extent to which increased costs are passed on to customers), (iv) minor in relation to removable covers for industrial process equipment (as for RO1), (v) major in relation to technical textiles for medical applications (given the limited ability of companies to pass on increased costs to customers) and (vi) minor in relation to technical textiles for transport vehicles (given the high extent to which increased costs are passed on to customers).<br>• Consumer surplus losses resulting from price changes associated with substitution in comparison to other TULAC and technical textile sub- |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | | | sectors are (expected to be) (i) minor in relation to outdoor technical textiles (as for RO1), (ii) minor in relation to architectural membranes, other tensile fabrics and other construction applications (as for RO1), (iii) minor in relation to filtration and separation media (given the low value of products placed on the EU market compared to other TULAC and technical textile sub-sectors, despite the expectation that products will largely be replaced by PFAS-free products and costs will largely be passed on to customers), (iv) very minor in relation to removable covers for industrial process equipment (as for RO1), (v) minor for technical textiles for medical applications (given that an increased share of products will be replaced by PFAS-free products compared to RO1) and (vi) minor for technical textiles for transport vehicles (given the low value of products placed on the EU market compared to other TULAC and technical textile sub-sectors, despite the expectation that products will largely be replaced by PFAS-free products and costs will largely be passed on to customers).<br>• Medium welfare losses or additional costs as a result of lower functionality are expected, e.g. |

| **Use sector** | **Proposed derogation** | **Duration of derogation period, including substantiation** | **Cost impact of 5 and/or 12 year derogation periods** |
|---|---|---|---|
| | | | (i) negative impacts on the service life duration of outdoor technical textiles and associated costs for, e.g. repairing seams, as well as similar impacts in relation to e.g. permanent load-bearing architectural elements, and (ii) some negative impacts on e.g. filtration performance, service life duration and the energy efficiency of filtration processes relating to water treatment and purification.<br>• Employment losses are expected to be medium given that some producers of permanent load-bearing elements are expected to close business (e.g. as a result of the shrinking of the market for architectural membranes) and that producers of removable covers for industrial process equipment are expected to close business given that relevant products are expected to be replaced by non-textile products.<br>Conclusion: Moderate costs |
| **Broader industrial uses (Annex E.2.23.)** | | | |
| PFAS used in hydraulic fluids, solvents, catalysts, and processing aids | In light of sufficiently strong evidence pointing to a low substitution potential at EiF, derogations are proposed for:<br>• Ionic liquids used in industrial uses until 6.5 years after EiF (§5uu) | A 5**-year** derogation (with a transition period of 18 months) is proposed for: broader industrial uses as ionic liquids<br>A **12-year** derogation (with a transition period of 18 months) is proposed for: broader industrial uses as solvents | Ban with a transition period of 18 months and an assumed 5-year derogation period for all considered derogations:<br>Assuming that suitable alternatives will |

| Use sector | Proposed derogation | Duration of derogation period, including substantiation | Cost impact of 5 and/or 12 year derogation periods |
|---|---|---|---|
| | - Solvents used in industrial uses until 13.5 years after EiF (§5vv)<br>- Catalysts and processing aids used in industrial uses until 13.5 years after EiF (§5ww) | A **12-year** derogation (with a transition period of 18 months) is proposed for: broader industrial uses as catalysts and processing aids | be identified for the uses for which alternatives do not exist at EiF, and that economic impacts would arise due to identification of alternatives, the costs are expected to be lower than for RO1.<br>Ban with a transition period of 18 months and an assumed 12-year derogation period for all considered derogations:<br>Assuming that suitable alternatives will be identified for the uses for which alternatives do not exist at EiF, and that economic impacts would arise due to identification of alternatives, the costs are expected to be lower than for RO1.<br>Conclusion: moderate costs |

### Cumulative impacts

In addition to the use-specific impacts, the Dossier Submitters note that cumulative impacts can occur when multiple uses/products based on PFASs, when combined, lead to additional adverse effects on companies/sectors, and their ability to transition to alternatives to PFASs within the proposed time frames for derogations.

In submissions to the consultation on the Annex XV report, the Dossier Submitters have identified two types of situations where cumulative impacts are of particular concern.

Firstly, situations where a company (or a sector) uses various PFASs across a wide range of products for use downstream in multiple sectors and for multiple uses (see e.g. comment ID #3977). Alternatives will need to be assessed, designed and implemented for many uses in parallel, taking the specific functionality requirements of a wide range of customers and uses into account. The Dossier Submitters note that this could put a strain on the affected actors' resources for research and development, and could, consequently, lead to the abandonment of product segments where the required investments in substitution are not considered worthwhile given the combination of uncertainty of success and future market opportunities.

Secondly, situations where PFASs are simultaneously used for multiple applications of relevance to the same complex product or multiple complex products. Examples raised in submissions to the consultation on the Annex XV report include the automotive sector (see e.g. comment ID #7145), the aerospace and defense sector (see comment ID #8945), and non-road machinery (see comment ID #8974). Multiple components where PFASs (primarily fluoropolymers) currently play an important role are used in combinations to form complex products. As an example, 15-20% of 5 000 - 7 000 components in an automotive vehicle are stated to be directly or indirectly affected by a restriction of PFAS (comment ID #7145). These components are in many instances interdependent on each other, and the substitution of PFAS in one component can affect the overall functionality of the complex product. This interdependency of components adds another layer of complexity to the transition to alternatives to PFAS.

These cumulative impacts could lead to challenges for affected companies especially where no feasible alternatives have been identified yet, which is the case where the Dossier Submitters propose a 12-year derogation (in addition to the 18-month transition period).

Even though these types of cumulative impacts could occur, the Dossier Submitters do not consider them to be sufficiently strongly justified to alter the conclusion that a derogation period of 12 years is normally sufficient for industry to take benefit from technical progress and to carry out scientific R&D activities to find and deploy technically and economically feasible alternatives.

The Dossier Submitters do however recommend that these types of cumulative impacts are taken into consideration in an eventual review of the 12-year derogations.

### Overarching impacts on trade and competitiveness

Given the broad scope of the restriction and the high number of affected sectors, it is important to consider potential impacts on trade and competitiveness. As the extent of markets, number of competitors (and extent of changes in the number of competitors as a result of business closures), and implications on the prices of products, have been assessed in the different sector analyses to the extent possible, this section aims to provide an overarching picture on likely impacts on EEA markets and companies regarding trade and competitiveness.

For the purpose of this analysis, it has been considered that industry/trade organizations are particularly likely to provide insights on such types of impacts given their overarching perspective on their respective sector. Of all submissions from industry/trade associations based in the EEA (~530 submissions), around 200 are considered to provide information and/or statements on impacts on trade and competitiveness. Please note that most of the information provided through the consultation comments is qualitative and therefore the Dossier Submitters have been unable to perform a quantitative analysis on impacts on trade and competitiveness - and as such, this reduces the level of confidence in estimating the magnitude of the impacts. However, a low number of comments contained substantiated information (e.g. comment IDs #5390, 6362, 7993, 8199, 8587, 8748, 8912, 9023, 9262, 9314), which was incorporated in the analysis.

The Dossier Submitters note that impacts on trade and competitiveness are likely to occur in several sectors in case of a full ban on PFAS, like RO1. A ban on PFAS compounds may distort global markets and render many European industries disadvantaged in international markets. Non-EEA manufacturers, not affected by such restrictions, would gain an advantage not only in supplying EEA markets (when PFAS are used in the production process but not in the final product) but also in global trade.

The Dossier Submitters note that the implications on competition from imports into the EEA are pronounced when PFASs are only used in the production process (e.g. as a process chemical or in production equipment) but are not present in the end-product. One example of this is in chrome plating, where PFAS surfactants are used to lower the surface tension of the plating solution and reduce aerosol emissions, but do not remain in the plated product. In such cases (which are generally covered by derogations in RO2) a full ban on PFASs (RO1) in the EEA would risk providing advantages to non-EEA producers who would be able to produce these products or complex products and distribute them on the EEA market. In extreme cases, this could lead to EEA producers having to close their production or to relocate outside of the EEA. On the other hand, the negative impacts of a restriction on users downstream would be mitigated by imports from outside of the EEA.

The main issues concerning trade and competitiveness on the global market, as described by stakeholders (e.g. comment IDs #5390, 6362, 7993, 8199, 8587, 8748, 8912, 9023, 9262, 9314) and identified in sector-specific assessments, are summarized below.

- ***Increased costs, reduced product performance, and shorter product lifespan.*** According to trade associations, European producers risk facing challenges redirecting their product portfolios towards PFAS-free alternatives in case of a ban. As described in the sector-specific assessments, in a wide variety of uses PFASs provide performance features critical for product integrity, safety, and longevity, that are challenging to match with alternatives. Where alternatives provide a sufficient level of performance to meet functionality requirements, their use nevertheless often leads to differences in the characteristics and service life duration of the product. Where alternative-based products can be supplied to the market, a ban on PFAS might – depending on the product – lead to increased operational expenditures for downstream users, reduced product performance, shortened product lifespans, and/or increased maintenance costs. (Such impacts are described in the sector-specific assessments.) In addition, substitution to alternatives is in numerous cases expected to lead to increases in the price of the final product to enable manufacturers to amortize costs incurred in relation to R&D and substitution. Such changes are deemed to be particularly pronounced on the EEA market where the price elasticity of demand for a product is low and the profit margins of producers prior to a ban were already low.

These differences in price and functionality could make it challenging for EEA companies to compete on the global market. Products with e.g. reduced performance and shortened product lifespans, offered at a higher cost compared to PFAS-based products will likely not be of interest to global customers. EEA producers might thus need to carefully consider their pricing on the global market to match or even undercut the prices of non-EEA suppliers to create interest of non-EEA customers in their product. This might come at the expense of increased producer surplus/profit losses for EEA companies or potentially even higher increase in the product price on the EEA market as companies might try to preserve the profitability of their business by balancing reduced profit margins on the global market with higher profit margins on the EU market.

Regardless of the product price, some stakeholders expect that differences in the characteristics of the product would make it challenging to compete on the global market (in the absence of comparable regulatory initiatives in other parts of the world). Such impacts are, for example, expected in relation to filtration and separation media (as described in section E.2.22). A German manufacturer of PVDF tubular membranes and tubular modules for ultrafiltration (comment ID #7996) reports that a full ban of PFAS would force the company to switch to using existing/earlier generation materials such as PES. Switching to the use of PES would however imply that the company "*would no longer have a competitive product on the market, resulting in a loss of market share*" in the global market. According to the company, customers outside of the EU, especially in China and the United States would stop buying their products and buy membranes supplied by local manufacturers instead. Similar impacts are described by a confidential comment.

- ***Implications on product innovation.*** Stakeholders indicate that the R&D efforts required to transition to alternatives (including re-engineering, re-qualification and recertification of existing product portfolios (see e.g. comment ID #6362) could crowd out other product innovation efforts. The capacity for innovation could also be impacted by declining profit margins due to increased costs and/or lower product performance (as indicated above). In addition, PFASs play an important role in product innovation in a wide range of sectors and a restriction on PFAS would thus close some currently planned and/or future routes of innovation.

- ***Disruption of critical supply chains.*** PFASs are often integral to components like seals, refrigerants, coatings, and lubricants used in a wide array of products. There is a risk that, without properly defined derogations, entire production processes could collapse because alternative materials are not yet available or fail to meet strict technical or safety standards. An example raised by stakeholders (e.g. comment ID #7993) is the implications on the chemical manufacturing sector, where PFASs are used in core pieces of equipment (e.g. in sealing applications). If there are no feasible alternatives available for certain uses, and relevant derogations are not included in a restriction, production in the sector would be negatively affected. This would not only harm the chemicals manufacturing sector but also downstream sectors and thus the ability of EEA companies in these sectors to compete on domestic and international markets.

- ***Risk of non-compliant products distorting competition.*** Stakeholders (e.g. comment IDs #4471, 7518, 9431, 9523) raise concerns about non-compliant products (imported as well as domestically produced) entering the market and distorting competition to the disadvantage of compliant companies, highlighting the need for standardized analytical methods and sufficient enforcement activities.

The Dossier Submitters note these concerns related to trade and competition and conclude, based on the information provided by stakeholders and information in the sector-specific assessments, that the concerns will largely be mitigated by:

- comprehensive, well-designed derogations, as presented in the sector-specific assessments, and
- a practical and enforceable restriction (section 2.5) supported by robust market enforcement activities by national enforcement agencies.

Nevertheless, some impacts on competitiveness on the global market as a result of changes in the characteristics of products, e.g. in relation to the service life duration, are expected even with comprehensive, well-designed derogations. The Dossier Submitters note however that negative implications on trade and competitiveness might be partially mitigated if other jurisdictions adopted PFAS restrictions with a scope similar to this proposed restriction. If similar actions are taken in other jurisdictions, EEA companies could potentially benefit from being early adopters of alternatives to PFASs. Such advantages to early adopters of alternatives have been described in (e.g.) the sector-specific assessment for TULAC (see Annex E.2.2.4.1), where firms in the consumer apparel and home textiles sub-sectors that have not yet substituted away from PFAS are deemed to have their ability to pass on costs to consumers limited by the competition from companies that have already substituted. Expected impacts could range from increased producer surplus losses for such companies due to the need to internalize increased costs up to the inability to substitute for financial viability reasons and consequently the need to close business.

### 2.4.1.2. Economic impacts on public actors: Enforcement and certification costs

Enforcement costs

In addition to economic impacts on manufacturers of PFAS-containing articles and on customers, a restriction on PFASs will also lead to costs for public authorities. Enforcement authorities will incur costs for enforcing the restriction, which includes administrative and analytical or testing costs. Administrative costs thereby consist of incremental costs for staff salaries, materials, equipment and overhead costs, while analytical costs consist of the cost for developing testing methods and conducting tests for various products to determine whether they meet the requirements of the restriction.

As noted in other Annex XV dossiers, e.g. the Annex XV dossier on intentionally added microplastics (ECHA, 2019a), the incremental **administrative costs for restrictions** are estimated by ECHA to equal approximately €55 000 per year based on a fixed budget approach assuming that enforcement authorities have a limited budget for enforcement, which they allocate to enforcing restrictions on the basis of the expected risk of non-compliance. The Dossier Submitters recognize the limitations of this approach. In the absence of other estimates, it is however assumed – in line with the approach employed in the Annex XV dossier on intentionally added microplastics (ECHA, 2019a) which also covers multiple sectors – that enforcement authorities would incur administrative enforcement costs of €55 000 per year for each of the sectors for which a restriction is proposed.

As for the Annex XV dossier on intentionally added microplastics, the approach of assuming a cost of €55 000 for each sector (instead of the restriction as a whole) has been taken to reflect the broad scope of the restriction which impacts diverse uses in several different sectors which may require diverse enforcement expertise. As highlighted in ECHA (2019a), this approach might result in an overestimation of costs to public actors as the administrative cost estimate of €55 000 refers to one restriction entry and has not been differentiated on the basis of a narrow or broad scope and the level of complexity of a restriction. A further potential source of overestimation is – as noted in ECHA (2019a) – that enforcement costs are assumed to be incurred annually from the EiF date until the end of the assessment period. This is seen as a source of overestimation as non-compliance, and therefore, enforcement efforts (and related costs) to ensure compliance decline with time as supply chains become familiar with the restriction requirements. As a result, enforcement costs are deemed to be highest immediately after EiF and to approach zero towards the end of the assessment period.

For several uses considered in this dossier, enforcement activities for already existing legislations, e.g. the restriction on PFOA, its salts and PFOA-related substances, are furthermore deemed to overlap with enforcement of a restriction of PFASs. Due to these possible synergies, enforcement costs for several uses might be overestimated. Overall, enforcement costs are however deemed negligible in comparison to other costs resulting from the restriction.

In addition to administrative costs, analytical costs will be incurred for developing testing methods and conducting tests for various products. These costs could however not be estimated.

Certification

In addition to enforcement costs, a restriction of PFASs is expected to lead to administrative costs for public authorities in relation to the **certification** of products based on alternatives.

For several uses, companies will incur costs in relation to re-certification and re-approval of their products. Such costs are deemed to be relevant for the companies and considered in the corresponding sections of the dossier. Some of those re-certification/re-approval processes are related to regulatory requirements and will thus also result in additional administration costs for national authorities.

Regulatory requirements range from internal documentation to complete re-approval. As such, additional costs for public authorities are anticipated. Due to several uncertainties, e.g. about the requirements, existence of fees and charges to cover additional public costs and number of companies that will apply for certification of re-developed products, the total costs to public authorities incurred in relation to a restriction of PFASs could not be estimated.

In addition, and in line with the fixed budget approach for enforcement costs, annual costs to public authorities are deemed to be bound to fixed budgets with limited room for extending processing capacities (at least in the short term) due to budgetary constraints and challenges with extending available staff capacity by hiring workers with the relevant expertise. As such, administrative costs to public authorities are deemed to be negligible in comparison to other costs resulting from the restriction.

### 2.4.2. **Human health impacts**

The impact of continued use of, and increased human exposure to, PFASs on human health that can be prevented through the proposed restriction options cannot be quantified because of limited, or missing, data to assess (i) the hazard of many of the individual PFAS substances; (ii) the associated thresholds below which exposure is not expected to lead to adverse health effects, if such limits exist, (iii) the combined effects of co-occurring PFASs, and (iv) the prediction of future human exposure levels. However, for a large part of PFAAs sufficient information is available to suggest that negative health impacts (see Table 12) in the general population already occur in highly exposed communities or will occur at some point in the future due to increasing pollution stocks in the environment.

**Table 12. Current health impacts in the general population due to exposure to the most analysed PFASs (see Annex B.5.3.).**

| **Health impact category** | **Type of health effects** |
|---|---|
| Immune outcomes | Reduced vaccine responses in children |
| | Increased propensity of lower respiratory tract infections |
| | Increased risk of atopic dermatitis |
| | Asthma- and allergy-related outcomes (hypersensitivity) |
| Liver toxicity and metabolic disruption | Increased serum alanine transferase (ALT) which is a marker of liver toxicity and fatty liver diseases |

| **Health impact category** | **Type of health effects** |
|---|---|
| | ▨ Increased total and LDL-cholesterol |
| | □ Increased risk of cardiovascular diseases |
| Reproduction and development | ▨ Reduced birth weight |
| | □ Effects on male and female fertility |
| | □ Effects on sex hormones and related outcomes |
| | □ Preterm delivery |
| | □ Miscarriage and preeclampsia |
| Carcinogenicity | ▨ Increased risk of renal cell carcinoma and kidney cancer |
| Thyroid functioning | □ Thyroid disease or changes in thyroid hormones |

Table legend

| | |
|---|---|
| ■ | Evidence of an association between exposure and health effect, strengthened by new studies. |
| ▨ | Limited evidence of an association between exposure and health effect, supported by new studies. |
| □ | Suggestive evidence of an association between exposure and health effect, inconclusive new studies. |

Stakeholders have also provided input in the consultation on the Annex XV report to express their concern about the health impacts of PFASs, and to highlight the associated benefits of the restriction (e.g. comment ID #6185, 6282, 7331, 7447, 7523, 8863, 9161, 9367, 9553, 9554). Several stakeholder responses (e.g. comment ID #7146, 7642, 9267, 9560), including experts in the field such as the European Society of Endocrinology (comment ID #9560), have confirmed that PFASs that have been studied have been associated with the adverse health impacts shown in Table 12. In addition to the impacts mentioned in Table 12, the European Society for Paediatric Endocrinology (comment ID #9228) highlighted that existing peer-reviewed studies have established links between PFAS exposure and various childhood illnesses, including endocrine cancer, obesity, distributed timing of puberty, impaired fertility, neurodevelopment alterations and numerous rare diseases. The stakeholder also noted that children can be exposed to PFASs through multiple widespread and unavoidable sources such as the placenta, breast milk, toys and plastic bottles. Additionally, the European Society of Endocrinology (comment ID #9560) pointed out a potential link between exposure to PFOA and PFOS and reduced immune response to vaccinations during the COVID-19 pandemic. These findings underscore growing concerns about the pervasive nature of PFAS exposure and its potentially serious implications for human health, especially for vulnerable groups such as children. They also highlight a need for continued research and stronger regulatory measures to mitigate these risks.

PFASs released during production or during the product life stage remain in the environment and will remain a source of exposure for generations to come. For some PFASs, specifically those already phased out or restricted under REACH in the EU, combined exposure already exceeds existing limit values for highly exposed communities in the population (section 1.1.4.9; (Bil et al., 2023; Olsen et al., 2007; Richterová et al., 2023; Schillemans et al., 2023)). Any additional exposure to other PFASs, that are to date less well investigated but for which comparable effects have already been demonstrated or can be expected because of structural similarities, will contribute to the magnitude of negative human health impacts in the future. Therefore, exposure to PFASs needs to be minimised.

As emission prevention techniques are missing or too expensive, emissions of PFASs from industrial and consumer uses to the environment cannot be avoided completely. Once in the environment it is very costly and impractical or even impossible to remove PFASs through remediation. The combination of these factors creates a risk of long-term, and potentially irreversible health damage at the global scale, which can to some extent be limited by the proposed restriction. In addition to the aforementioned physical health effects, the proximity to environmental contamination hotspots may affect residents' psychosocial health as affected communities may face a spectrum of negative mental and physical effects related to uncertainty around long-term health outcomes (Prior et al., 2019).

In summary, the expected impact of the proposed restriction options are the avoided negative human health effects associated with the continued use of PFASs. The magnitude of the impact of continued use of PFASs on human health cannot be quantified but current combined exposure to some regulated PFASs already exceeds existing limit values. Therefore, due to structural similarities and a similar hazard profile, (co-)exposure to other, non-regulated, PFASs should be minimized. This implies that restriction option RO1, that reduces the increase of the environmental pollution burden of PFASs the most, compared to the baseline scenario, will result in the highest benefit to society in terms of avoided long-term human health impacts resulting from exposure to PFASs.

## 2.4.3. **Environmental impacts**

### 2.4.3.1. Approach to environmental impact assessment

As discussed in section 1.1.6, in this restriction proposal, PFASs are treated as non-threshold substances for the purpose of risk assessment and their releases are used as a proxy for risk. The following approach to environmental impact assessment therefore focuses on estimating emissions.

Emissions to the environment are estimated for (i) the manufacturing phase, (ii) the use phase, and (iii) the End of Life (EoL) phase. Generally, the tonnage base for estimating emissions during the use phase is lower than the total PFAS tonnage which is put on the market in a specific year. This is because the tonnage volume for deriving emissions in the use phase does not include PFAS emissions which already occurred during the manufacturing phase. In relation to the applications of fluorinated gases (also in the transportation sector), PFAS refilling of equipment occurs during the use phase. Due to this, the proposed approach to calculate use phase emissions takes the total technical PFAS stock which is in use in a particular year as the tonnage base relevant for quantifying emissions during the use phase. Tonnage and emission estimates were projected to the future using available information about the expected economic growth for the respective use. Following to this, emission estimates per year were calculated applying emission factors to either estimates of manufactured tonnage or tonnage volumes in the use and End of Life phase, respectively. For some uses, industry specific information on appropriate emission factors was available and could be used. For the other uses, industry specific information was lacking. Therefore, the Dossier Submitters applied default parameters for environmental release rates according to the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16. These environmental release category (ERC) factors describe the broad conditions of use from the environmental perspective, considering also default assumptions about the service-life of uses or applications.

Emissions were assessed for the environment as a whole (one-compartment model), based on the aggregation of emissions across individual compartments (air, water, soil). This approach was chosen for different reasons.

- First, considering the complexity of the dossier (in particular the large number of use sectors), the one-compartment model ensures a sufficiently harmonized and consistent approach to environmental impact assessment, while still exploiting all available information on emissions and releases.

- Second, the high persistence of PFASs is considered the core concern underlying this restriction proposal. As a result of persistence, a continued use of PFASs will inevitably cause environmental exposure to increase further over time, irrespective to which environmental compartment emissions will be released.

- Third, since the one-compartment model is based on assessments of releases to individual compartments, a disaggregation of emission estimates remains possible for the different uses should this seem useful.

Note that, where adding up the separate ERC factors to water, soil, and air would exceed 100%, an overall emission factor to the environment of 100% was assumed to ensure that over-estimation errors of emissions are minimized.

The expected total emissions avoided of a particular RO in comparison to the baseline scenario is used as a proxy for the expected reduction of environmental impacts, adopting a time path of 30 years. Sections 2.4.3.2 and 2.4.3.3 show results for the baseline and the defined restriction options, and for a time path of 30 years. Information about total emissions based on a 30-year time path is provided in Annex E. The time path of emissions considers available information about growth rates in different sectors. The start year for the assessment is 2020 (first year of data documentation of emissions). Assuming the restriction to enter into force in 2025 at the earliest, environmental impacts were calculated from 2025 onwards, and considering a transition period of 18 months. Furthermore, in line with earlier restriction proposals addressing PBT and vPvB chemicals, the Dossier Submitters assumed a discount rate of 0% for emissions.

In addition to the baseline, environmental impacts are determined for two restriction options. First, under RO1 the impact of a full ban, entering into force after a transition period of 18 months, is analysed. Under RO1, no derogations are considered. Second, under RO2 environmental impacts of a ban in combination with defined, use-specific derogations are analysed. The derogations considered under RO2 are (i) derogations of a duration of five years and (ii) 12-year derogations, both taking effect after the end of the transition period, and (iii) time-unlimited derogations. Environmental impacts of RO1 and RO2 are assessed quantitatively. When assessing the environmental impacts for RO2, the assessment approach distinguishes between two situations. First, when quantitative emission data of specific PFAS uses are available, expected additional emissions from a proposed derogation can be quantified straightforwardly. In many cases, however, emission data at sub-use level are largely lacking. In such cases, the expected additional emissions of a proposed derogation are approximated using expert information about the applications covered by a derogation. Such qualitative information includes, for example, information about the environmental release factors applied to certain PFAS groups, or information about the relevance of a certain application in the assessed group of uses. Using the expert judgement allows to estimate additional emissions associated with the relevant derogation.In several cases, yearly tonnage and emission estimates vary within a considerably broad range, indicating that there is some uncertainty (see also Annex F). For the assessment of environmental impacts under the baseline and under the ROs mid-point emission estimates where used. For sectors for which information about high and low tonnage estimates was lacking, available values were used as mid-point estimates.

The Dossier Submitters opted for the use of one value, i.e. the mid-point value, for ease of understanding and for facilitating the comparison of results across sectors/uses. Upper and lower bound emission estimates resulted from available information and reflect the best available knowledge for each sector/use. In several cases, the difference between the upper and lower bound emission estimates is large. It is then common to use mid-point values instead of the upper and lower bound values. The choice of using mid-point values as a basis when assessing the environmental impacts of different restriction options (ROs) is also motivated by the consideration, noted in section 1.1.6, that PFASs should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances. As a result, emissions should be minimized as all emissions pose a risk and adverse impacts for society cannot be ruled out below a specific threshold. Emissions can therefore be used as a proxy for risk and a cost-effectiveness analysis is the commonly applied approach for evaluating regulatory options for such substances. In light of this, the Dossier Submitters consider that information on the effectiveness of ROs in reducing emissions in comparison to the baseline (in percentage terms) is of higher importance to the proportionality assessment than the reduction in absolute terms (which is nevertheless reported). Furthermore, the Dossier Submitters consistently take the mid-point value of emission estimates as a basis for the baseline as well as all assessed ROs for all sectors/groups of uses and approximate the emissions associated with derogations in comparison to that baseline. The Dossier Submitters consider that the choice of the value (mid-point, lower or upper bound value) does not impact the conclusions on effectiveness. While the use volume and emissions estimated under the baseline would be lower in absolute terms when, for example, using the lower bound value, the emission reduction estimated for RO1 would also be lower in absolute terms. As such, no differences in the effectiveness is expected. Equally, the volume of emissions associated with a derogation is approximated based on the available data on volumes used for specific sub-uses (and where necessary expert judgement on the share that relates to the derogation). While the absolute amount of emissions associated with a derogation would therefore differ depending on the value (mid-point, lower or upper bound value) used for the assessment, the impact in relative terms, i.e. in comparison to the baseline, is the same

### 2.4.3.2. Baseline environmental impacts

Table 13 below summarizes the expected total emissions resulting from a continued use of PFASs, and for an assumed time path of 30 years. Emission estimates capture assumptions about use (group)-specific growth rates as discussed in Annex E. Estimates are shown for different uses assessed in Annex E, and for the EU as a whole (being the aggregate of all uses).

**Table 13. Total PFAS use and environmental emissions under the baseline scenario for different PFAS uses (30 years), and fraction of emissions in relation to PFAS use.**

| **PFAS use** | **PFAS use [t]** | **Emissions [t] with EoL** | **Emissions [t] without EoL** | **Fraction of emissions compared to PFAS use [%]*[a]** |
|---|---|---|---|---|
| TULAC | 3 780 157 | 664 871 | 631 588 | 17.6 (16.7) |
| Food contact materials and packaging | 1 198 801 | 58 804 | 49 695 | 4.9 (4.1) |
| Metal plating and manufacture of metal products | 22 337 | 1 013 | 1 011 | 4.5 (4.5) |
| Consumer mixtures | 2 496 | 912 | 900 | 36.5 (36.1) |
| Cosmetics | 17 475 | 1 165 | 780 | 6.7 (4.5) |
| Ski wax | 22 | 14 | 13 | 66 (58) |
| Applications of fluorinated gases | 2 837 008 | 1 804 914 | 1 478 345 | 64 (52) |
| Medical devices | 829 278 | 387 686 | 383 035 | 47 (46) |
| Transport*[b] | 1 606 016 | 738 478 | 600 233 | 46 (37) |
| Electronics and semiconductors | 2 199 106 | 94 277 | 72 912 | 4 (3) |
| Energy sector | 11 243 057 | 470 246 | 363 953 | 4.2 (3.2) |
| Construction products | 787 293 | 241 400 | 219 534 | 30.7 (27.9) |
| Lubricants | 392 568 | 100 108 | 97 266 | 25.5 (24.8) |
| Petroleum and mining | 264 | n.a.*[c] | 59 | (22.5) |
| Printing applications | 14 461 | 722 | 702 | 5 (4.9) |
| Sealing applications | 1 317 296 | 29 086 | 22 724 | 2.2 (1.7) |
| Machinery applications | 34 432 | 1 265 | 1 025 | 3.7 (3.0) |
| Other medical applications | 94 518 | 76 626 | 76 507 | 81.1 (80.9) |
| Military applications*[d] | 284 297 | 69 099 | 38 014 | 24.3 (13.4) |
| Explosives | 22 009 | 1 664 | 1 657 | 7.6 (7.5) |

| **PFAS use** | **PFAS use [t]** | **Emissions [t] with EoL** | **Emissions [t] without EoL** | **Fraction of emissions compared to PFAS use [%]*a** |
|---|---|---|---|---|
| Technical textiles | 614 665 | 62 464 | 59 588 | 10.2 (9.7) |
| Broader industrial uses | 71 867 | 9 618 | 9 409 | 13.4 (13.1) |
| **Total (all uses)** | **27 085 126** | **4 745 333** | **4 070 936** | **17.5 (15)** |

*[a] Percentage without EoL emissions is presented in brackets.
*[b] To avoid double-counting the values in this row do not include tonnage and emission estimates from applications of fluorinated gases. These are counted in the row 'Applications of fluorinated gases'. For the sake of transparency though, the tonnage estimates, expected emissions, and the fraction of emissions related to applications of fluorinated gases in the transport sector are given in between brackets.
*[c] n.a. – not applicable (see corresponding sections in Annex B and E)
*****[d] Tonnage and emissions reported for the sake of completeness, but not included in the total to avoid double counting as the uses are already covered under other uses.

In addition to emissions which occur during the use phase of products containing PFAS, PFASs are emitted during the production phase of these products and at the end of the life cycle, i.e. during the waste phase. Yearly emission estimates for PFASs during production of products containg PFAS were derived from production tonnage estimates provided by industry, multiplied with ERC factors (see Annex B for further details). The projections underline that the total environmental impacts arising from PFAS use, expressed in terms of total emissions in the assumed 30-year period (2025-2055), account for about 4.7 million tonnes including end of life emissions (4.1 million tonnes without end of life emissions). It is important to note that this estimate is, for several reasons, likely a large underestimation of true emissions. First, for many sectors emission estimates were derived from tonnage values and environmental release factors (ERCs). The latter are determined for organic substances and likely underestimate the emissions of PBT/vPvB substances like PFASs. Second, there are processes which do not use PFASs but emit PFASs, such as, for example, PVC production and aluminium and magnesium production. Emissions from these processes are not included in the assessment. In addition, the timeline adopted for the assessment (30 years, starting in 2025) is likely much too short to cover long-term emissions arising from products at the end of life, and from landfilling/waste.

### 2.4.3.3. Environmental impacts of restriction options

Environmental **emissions under a full ban (RO1)**, and the fraction of the expected emission reduction compared to the baseline scenario, are summarized in Table 14. For calculating the expected emission reduction, the assumed entry-into-force year of the restriction dossier is 2025. Assuming a standard transition period of 18 months, RO1, i.e. a full ban, is expected to be implemented in 2027. All emission estimates represent mid-point values. The emissions related to RO1 in Table 12 are the remaining emissions during the transition period.

Table 14 shows the effectiveness of the restriction proposal as a whole for a full ban (RO1) and a ban with use-specific derogations (RO2) for all use sectors over the assessment period (2025-2055), excluding manufacturing. Overall, RO1 is the most effective restriction option, leading to an emission reduction of 95.7% compared to the baseline. The effectiveness of RO2 is with 83% (82%) slightly lower due to granting mostly time-limited use-specific derogations for 5 to 12 years in addition to the 18 months transition period, with a small difference between accounting for emissions with and without the end-of-life (EoL) phase.

**Table 14. Environmental emissions under RO1 and RO2 for a 30-year period (2025-2055), and fraction of emission reduction compared to the baseline.**

| PFAS use | Emissions RO1 with EoL [t] | Emissions RO1 without EoL [t] | Reduction of emissions under RO1 compared to the baseline with EoL [%] | Reduction of emissions under RO1 compared to the baseline without EoL [%] | Emissions RO2 with EoL [t] | Emissions RO2 without EoL [t] | Reduction of emissions under RO2 with EoL compared to the baseline [%] | Reduction of emissions under RO2 without EoL compared to the baseline [%] |
|---|---|---|---|---|---|---|---|---|
| TULAC | 30 594 | 29 063 | 95 | 95 | 37 381 | 36 847 | 95 | 95 |
| Food contact materials and packaging | 2 022 | 1 709 | 97 | 97 | 2 441 | 2 054 | 96 | 96 |
| Metal plating and manufacture of metal products | 65 | 65 | 94 | 94 | 114 | 114 | 91 | 91 |
| Consumer mixtures | 59 | 58 | 94 | 94 | 59 | 58 | 94 | 94 |
| Cosmetics | 74 | 50 | 94 | 94 | 74 | 50 | 94 | 94 |
| Ski wax | 1.4 | 1.2 | 90 | 91 | 1.4 | 1.2 | 90 | 91 |
| Applications of fluorinated gases | 86 031 | 70 465 | 95 | 95 | 306 806 | 290 578 | 83 | 80 |
| Medical devices | 11 232 | 11 097 | 97 | 97 | 12 029 | 11 749 | 97 | 97 |
| Transport | 41 080 | 33 390 | 94 | 94 | 291 574 | 236 632 | 61 | 61 |
| Electronics and semiconductors | 2 046 | 1 582 | 98 | 98 | 19 387 | 14 671 | 79 | 80 |
| Energy sector | 2 398 | 1 856 | 99 | 99 | 43 274 | 31 215 | 90 | 90 |
| Construction products | 10 306 | 9 372 | 96 | 96 | 11 086 | 9 886 | 95 | 95 |
| Lubricants | 4 274 | 4 152 | 96 | 96 | 38 006 | 36 927 | 62 | 62 |
| Petroleum and mining[a] |  | 3.3 | n.a. | 94 |  | 3.4 | n.a. | 94 |
| Printing Applications | 25.6 | 24.9 | 96 | 96 | 142 | 139.5 | 80 | 80 |

| **PFAS use** | **Emissions RO1 with EoL [t]** | **Emissions RO1 without EoL [t]** | **Reduction of emissions under RO1 compared to the baseline with EoL [%]** | **Reduction of emissions under RO1 compared to the baseline without EoL [%]** | **Emissions RO2 with EoL [t]** | **Emissions RO2 without EoL [t]** | **Reduction of emissions under RO2 with EoL compared to the baseline [%]** | **Reduction of emissions under RO2 without EoL compared to the baseline [%]** |
|---|---|---|---|---|---|---|---|---|
| Sealing applications | 1 181 | 923 | 96 | 96 | 9 939 | 7 765 | 66 | 66 |
| Machinery applications | 51 | 42 | 96 | 96 | 432 | 350 | 66 | 66 |
| Other medical applications | 6 590 | 6 580 | 91 | 91 | 20 369 | 20 337 | 74 | 74 |
| Military applications[b] | 1 867 | 1 027 | 97 | 97 | 19 239 | 10 584 | 72 | 72 |
| Explosives | 60 | 60 | 96 | 96 | 82 | 82 | 95 | 95 |
| Technical textiles | 1 709 | 1 630 | 97 | 97 | 9 946 | 9 495 | 84 | 84 |
| Broader industrial uses | 390 | 382 | 96 | 96 | 3 062 | 3 035 | 68 | 68 |
| **Total (all uses)** | **200 189** | **172 505** | **96** | **96** | **825 443** | **722 573** | **83** | **82** |

[a] See corresponding sections in Annex B and E); [b] Reported for the sake of completeness, but not included in the total to avoid double counting as the uses are already covered under other uses.

A full ban of PFAS use (RO1) leads to a reduction of total emissions of about 96% in all use sectors. Due to the transition period of 18 months, during which emissions continue, RO1 does not lead to a full elimination of PFAS emissions. For some sectors, the reduction of total emissions is close to 100%.

In addition to a ban of all PFASs, a restriction option which considers use-specific derogations is considered (RO2). Under RO2, use-specific derogations are proposed for either 5 years (after the end of the transition period), for 12 years (after the end of the transition period), or without a time limit (for instance if existing national safety standards or building codes limit the use of alternatives to fluorinated gases). Use-specific derogations cause PFAS emissions to continue over time. The determination of extra emissions in case of a derogation (based on the approach described in section 2.4.3.1) also allows to assess effectiveness at the level of the restriction option (RO2) at use level as shown in Table 14. The approach is described in detail in Annex E.

In this way the expected additional emissions of restriction options proposing use-specific derogations can be quantatively compared to RO1 such that the evaluation is sufficiently transparent and consistent across uses. As noted in section 2.5.2, concentration limits are established to prevent any intentional, i.e. technically meaningful uses of PFASs. As such, the effectiveness of RO2 is driven by the proposed derogations rather than the concentration limits.

In the following, the **evaluation of RO2** is presented for each use sector.

### a) Evaluation of environmental impacts of RO2 relating to textiles (TULAC)

(i) *Proposed derogation: PPE in professional apparel*

- *Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I*
- *Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers*
- *Impregnation agents for re-impregnating of articles referred to above*

A 12-year derogation is proposed. The derogation covers mainly fluorpolymers and further PFPEs. RO2 achieves a mean total PFAS emission reduction (with EoL) of about 627 490 t compared to the baseline. The derogation can, therefore, be expected to reduce the effectiveness of the restriction to about 95%. The extra emissions of RO2 compared with RO1 are estimated to be 6 787 t over 30 years.

### b) Evaluation of environmental impacts of RO2 relating to food contact materials and packaging

(i) *Proposed derogation:*

  i. *Polymer processing aids used in flexible plastic film extrusion (for food and non-food applications)*
  ii. *non-stick coatings in industrial bakeware*

The derogations cover fluoropolymers and are proposed for a duration of 5 years. RO2 with the two proposed derogations together achieves a total PFAS emission reduction with EoL of about 56 363 t (without EoL 47 641 t) compared to the baseline. The additional emissions compared to RO1 are 419 t (345 t without EoL emissions). The derogations can, therefore, be expected to reduce the effectiveness of the restriction to about 96%.

### c) Evaluation of environmental impacts of RO2 relating to metal plating and the manufacture of metal products

(i) *Proposed derogation: Hard chrome plating*

The derogation is proposed for a duration of 5 years. Considering the available **weak evidence on emissions from hard chrome plating**, expected additional emissions resulting from the derogation compared with emissions under RO1 can be expected to be 49 t for a period of 30 years (2025-2055, see Annex E.2.4.). The derogation is, therefore, expected to reduce the effectiveness of the restriction only slightly, i.e. from 94% under a full ban (RO1) to 91% under RO2.

### d) Evaluation of environmental impacts of RO2 relating to consumer mixtures

Same as for RO1 as no derogations are proposed.

### e) Evaluation of environmental impacts of RO2 relating to cosmetics

Same as for RO1 as no derogations are proposed.

### f) Evaluation of environmental impacts of RO2 relating to ski wax

Same as for RO1 as no derogations are proposed.

### g) Evaluation of environmental impacts of RO2 relating to applications of fluorinated gases

*(i) Proposed derogation RO2a: Refrigerants in low temperature refrigeration below -50 °C*

A derogation is proposed for 5 years after the 18-month transition period. Alternatives are not technically feasible. There is no specific data available on the additional emissions that would occur from this use-specific derogation although they can be expected to be relatively small. For the purposes of the impact assessment, it was assumed, based on expert judgement, that between 1 to 5% of the quantified emissions from industrial refrigeration would be associated with the use-specific derogation. This is because only a limited number of industrial and commercial applications require temperatures below –50 °C e.g. storage of material for medical or biochemical use, such as vaccines. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 701 tonnes including EoL emissions (636 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(ii) Proposed derogation RO2b: Refrigerants in laboratory test and measurement equipment*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives for the use are available and technically feasible for certain operating conditions. However, alternatives are considered to be less flexible with regards to their performance over typical operating temperature ranges.

There is no specific data available on the additional emissions that would occur from this use-specific derogation although they can be expected to be relatively very small. For the purposes of the impact assessment, it was assumed that, based on expert judgement, that between 0.01 and 1% of the quantified emissions from industrial refrigeration would be associated with the use-specific derogation). This is because the use is limited to laboratories and comprises very small volumes compared to the other applications, in particular fluorinated refrigerants. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 331 tonnes including EoL emissions (301 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(iii) Proposed derogation RO2c: Refrigerants in refrigerated centrifuges*

A derogation is proposed for 12 years after the 18-month transition period as no suitable alternatives are available. The suitability of alternatives is limited as a rotor failure (a reasonably foreseeable event) could result in a ruptured refrigerant system. Under these circumstances, the use of flammable refrigerants or high-pressure systems is not considered to be technically feasible based on safety considerations. However, suitable alternatives may be developed over the medium term.

There is no specific data available on the additional emissions that would occur from this use-specific derogation although they can be expected to be relatively small. For the purposes of the impact assessment, it was assumed, based on expert judgement, that between 0.01 and 1% of the quantified emissions from industrial refrigeration would be associated with the use-specific derogation). This is because the use is limited to laboratories and other small-scale installations. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 304 tonnes including EoL emissions (276 excluding EoL emissions) over the assessment period compared to RO1.*Proposed derogation: Refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months after EiF.*

*(iv) Proposed derogation RO2d: Refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months after EiF*

A derogation without a time limit is proposed to allow the continued use of PFASs as refrigerants, clean fire-suppressant agents and insulating gases in existing ‘in service’ equipment (defined as equipment placed on the market before the end of the 18-month transitional period). Whilst the derogation is open-ended in duration, in practice, the quantities derogated will progressively decline to zero as equipment that was placed on the market/installed prior to the end of the transitional period reaches the end of its service life and is replaced. HVACR, clean fire-suppression and switchgear equipment reliant on the use of fluorinated gases is currently widespread in the EEA and there are no suitable 'drop-in' alternatives to the use of fluorinated gases for existing equipment.

There is no specific data available on the additional emissions that would be associated with this use-specific derogation although they can be expected to be relatively large. For the purposes of the impact assessment, it was assumed, based on expert judgement and an average equipment service life of 15 years, that the quantified emissions from refrigeration (commercial, domestic and industrial) and air conditioning (mobile and stationary) would progressively decline to zero (linear function) over the 15 years after the 18-month transitional period. Therefore, a derogation for this specific use is estimated to result in additional emissions of 182 587 tonnes including EoL emissions (182 587 excluding EoL emissions) over the assessment period compared to RO1. There is no difference between the effectiveness estimates including or excluding end of life emissions as there are no end of life emissions associated with this derogation.

*(v) Proposed derogation RO2e: Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives.*

A derogation without a time limit is proposed for instances where existing national safety standards or building codes limit the use of alternatives to fluorinated gases, such as hydrocarbons, ammonia or $CO_2$. National safety standards and building codes that limit the use of alternative refrigerants, typically the maximum volume of flammable refrigerants (such as propane), still apply in some EEA countries. This is despite recent revisions to European standards that permit their use when safe to do so. It is expected that national and European standards will evolve progressively over time to allow greater use of alternatives to fluorinated gases. The time required to achieve a for these changes to be made substitution is, however, not known.

There is no specific data available on the additional emissions that would be associated with this use-specific derogation although they can be expected to be relatively large. For the purposes of the impact assessment, it was assumed, based on expert judgement, that the quantified emissions from stationary air conditioning would progressively decline to zero (linear function) over the 15 years after the 18-month transitional period. Therefore, a derogation for this specific use is estimated to result in additional emissions of 69 835 tonnes including EoL emissions (69 835 excluding EoL emissions) over the assessment period compared to RO1. There is no difference between the effectiveness estimates including or excluding end of life emissions as there are no end of life emissions associated with this derogation.

*(vi) Proposed derogation RO2h: Foam blowing agents in thermal insulation foam*

A derogation was tentatively proposed in the Annex XV report for a period of 12-years after the 18-month transition period. Based on information provided in the consultation on the Annex XV report, the derogation is considered to be appropriate and has to extended to include foam boards in addition to sprayed foam. While, suitable alternatives are considered to be available for certain applications, further research and development is needed in order to identify alternatives that are practical and safe for all current applications of fluorinated foam blowing agents. In particular, the safe processing of PU spray foam under in-situ conditions within a building is difficult due to a high risk of fire in the cases where hydrocarbons are used as alternatives. While water-blown foam can also be used, there are challenges with dimensional stability and insulating capability of the resulting foams. Substantiated arguments for the continued use of fluorinated gases in spray foams as well as in foam boards because of the insulating properties have been presented by several stakeholders in the consultation on the Annex XV report. The disadvantages with alternative foam blowing agents, in general, are sufficient that a broader derogation appears to be justified.

The derogation could potentially be limited to specific applications where alternatives are not appropriate e.g. hot water tanks, space applications, spray foam. However, the specific information required to limit the scope of the derogation more precisely in a sufficiently reliable way was not available.

There is no specific data available on the additional emissions that would be associated with this specific derogation although they can be expected to be relatively large. For the purposes of the impact assessment, it was assumed, based on expert judgement, that between 10 and 30% of the quantified emissions from foam blowing agents (closed and open cell) would be associated with the use-specific derogation. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 17 587 tonnes including EoL emissions (17 321 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(vii) Proposed derogation RO2i: Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required. The derogation does not apply to products intended for entertainment and decorative purposes for the general public.*

A derogation is proposed for 12 years after the 18-month transition period. Suitable alternatives are not available. The derogation is not intended to apply to products intended for entertainment and decorative purposes for the general public.

There is no specific data available on the additional emissions that would be associated with this specific derogation. For the purposes of the impact assessment, it was assumed, based on expert judgement, that less than 1% of the quantified emissions from all fluorinated gases would be associated with the use-specific derogation. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 3 001 tonnes including EoL emissions (2 458 tonnes excluding EoL emissions) over the assessment period compared to RO1.There are no EoL emissions reported for propellants.

*(viii) Proposed derogation RO2f: Fluorinated gases used as clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health*

A derogation is proposed for 12 years after the 18-month transition period. Potential alternatives are available but are associated with significant technical and risk-based limitations e.g. they can cause health effects, or may damage the assets to be protected. For certain sectors, for example aviation (#7699), there are also safety standards that need to be fulfilled, and thus substitution takes time, as the alternative has to be approved/certified.

The Technology and Economic Assessment Panel (TEAP) under the Montreal Protocol and its Fire Suppression Technical Options Committee (FSTOC) indicate in their latest progress report that it typically takes significantly longer than 10 years to identify and implement a new fire suppressant (UNEP, 2024). In the report stakeholders report that substantial research and development was required to develop clean fire suppressing agents based on fluorinated gases, suggesting that rapid development of non-PFAS alternative clean fire-suppressing agents that have low GWP and are not ozone depleting is unrealistic. Furthermore, FSTOC expressed concern that the proposed restriction could result in unpredictable negative impacts, undermining the achievements of the Montreal Protocol, that is phasing out the use of halons (ozone-depleting substances) and high GWP HFC as fire suppressants, since those are expected to remain the only alternatives for several fire suppression applications if other fluorinated gases are subject to REACH restrictions.

There is no specific data available on the additional emissions that would be associated with this use-specific derogation. For the purposes of the impact assessment, it was assumed, based on expert judgement, that between 1 and 5% of the quantified emissions from all fluorinated gases would be associated with the use-specific derogation. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 17 829 tonnes including EoL emissions (14 603 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(ix) Proposed derogation RO2j: Preservation of cultural paper-based materials*

A derogation is proposed for a time period of 12 years after the 18 months transition period. Potential alternatives need to be chemically inert in order to protect the sensitive objects. Comments to the consultation on the Annex XV report have confirmed that there are no suitable alternatives.

There is no specific data available on the additional emissions that would be associated with this specific derogation. For the purposes of the impact assessment, it was assumed, based on expert judgement, that less than 0.01% of the quantified emissions from all fluorinated gases would be associated with the use-specific derogation. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 30 tonnes including EoL emissions (25 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(x) Proposed derogation RO2g: Insulating gases in high-voltage switchgear (above 145 kV)*

The derogation is proposed for a time period of 5 years after the 18-month transition period. Alternatives are not yet suitable for all voltage ranges but are in the process of being developed. Fluorinated gases were introduced to replace $SF_6$ as insulating gas in electrical switchgear due to its high GWP. Recently, alternatives to fluorinated gases in these applications have been introduced and are in development for the full voltage range. Specifically, clean air technology has been introduced to replace both $SF_6$ and fluorinated gases as insulating gas in electrical equipment, together with dry air (mix of nitrogen and oxygen) and vacuum.

The required time for substituting fluorinated gases in this application is not known, although a comment to the consultation on the Annex XV report (#8906) supports the proposed derogation of 5 years, as this would allow for alternative technology to be implemented even for high voltages.

There is no specific data available on the additional emissions that would be associated with this specific derogation. For the purposes of the impact assessment, it was assumed, based on expert judgement, that less than 1% of the quantified emissions from all fluorinated gases would be associated with the use-specific derogation. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 1 164 tonnes including EoL emissions (954 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(xi) [Proposed derogation RO2k: use of fluorinated gases at the CERN research installation]*

A potential derogation is proposed for 12 years after the 18-month transition period. Based on information from the consultation on the Annex XV report it can be concluded that that technically and economically feasible alternatives are unavailable in the quantities required for use at the CERN research installation. The additional emissions associated with this derogation were reported in the consultation on the Annex XV report to be 952 tonnes over the assessment period compared to RO1 (including and excluding EoL).

### h) Evaluation of environmental impacts of RO2 relating to medical devices

(i) *Proposed derogation RO2a: Invasive medical devices (e.g. tubes and catheters)*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. The Dossier Submitters assume an equal distritution for PFAS use for invasive and implantable medical devices [comment #4604]. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 311 tonnes including EoL emissions (and 309 tonnes excluding EoL) over the assessment period compared to RO1.

(ii) *Proposed derogation RO2b: Implantable medical devices (including medical implants and meshes)*

The derogation is marked for consideration for a duration of 12 years after EiF of the restriction and the 18 months transition period. The Dossier Submitters assume an equal distritution for PFAS use for invasive and implantable medical devices (comment ID #4604). Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 311 tonnes including EoL emissions (and 309 tonnes excluding EoL) over the assessment period compared to RO1.

(iii) *Proposed derogation RO2c: Packaging for medical devices*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 175 tonnes including EoL emissions (and 34 tonnes excluding EoL) over the assessment period compared to RO1.

### i) Evaluation of environmental impacts of RO2 relating to the transport sector

*(i) Proposed derogation RO2a: Refrigerants in mobile air conditioning (MAC)-systems in i) light duty electrical vehicles ii) all other vehicles*

There is no specific data available on additional emissions that would be associated with this use-specific derogation although they can be expected to be relatively large. For the purposes of the impact assessment, it was assumed, based on expert judgement, that the emissions in the production and service life phase related to MAC will continue in the derogation period. Assuming a market share of 25% for light duty electrical vehicles implies that 25% of the emissions in the production and service life phase related to MAC will stop after year 5 from the entry into force, while 75% of the emissions in the production and service life phase related to MAC will continue in year 6-12 of the derogation period. Therefore, a derogation for this specific use is estimated to result in additional emissions of 198 089 tonnes including EoL emissions (159 015 tonnes excluding EoL emissions) over the 30-years assessment period compared to RO1.

*(ii) Proposed derogation RO2b: Refrigerants in transport refrigeration other than in*

*marine applications*

A derogation is proposed for 5 years after the 18-month transition period. The derogation will cause additional emissions of fluorinated gases. The expected additional emissions due to this derogation are all emissions in the production and service life phase related to refrigeration. The proposed derogation is for maintenance and refilling of equipment installed before EiF. The emissions are a maximum estimate, as it is reasonable to assume that new installations after EiF will choose PFAS free alternatives as the lifespan of the equipment normally would be longer than the derogation period. A derogation for this specific use is estimated to result in additional emissions of 9 642 tonnes including EoL emissions (8 800 tonnes excluding EoL emissions) over the 30-years assessment period compared to RO1.

*(iii)* *Proposed derogation RO2c: '(a) Vehicle systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles)] that are subject to EU vehicle type approval, where the type approval was obtained within 13.5 years after EiF (e.g. motor vehicles within the scope of Regulation (EU) 2018/858, (EU) 2019/2144 or Directive 2007/46/EC, agricultural and forestry vehicles with the scope of Regulation (EU) 167/2013, aircraft within the scope of Regulation (EU) 2018/1139 or (EU) 748/2012, watercraft within the scope of Directive 2013/53/EU or 2009/45/EC, and rail vehicles within the scope of Regulation (EU) 2016/797 or Directive (EU) 2016/798) OR (b) systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles)] in vehicles that are not within the scope of paragraph a, where the use of fluoropolymers or perfluoropolyethers are strictly necessary for safety or environmental performance of those vehicles. e.g. braking, restraint, lighting/signalling, driver assistance systems, emission control.*

A derogation is proposed for 12 years after the 18-month transition period. The derogation will cause additional emissions of fluoropolymers and perfluoropolyethers.

**No evidence is available** about the precise amount of additional emissions. Though the precise fraction of emissions is not known, it can be assumed it is up to 100% of the polymeric PFAS emissions, considering that the use is indispensable for a proper functioning of all transportation vehicles. Assuming a derogation of all polymeric PFAS use, the additional emissions compared to RO1 will be 7 621 t incl. EoL emissions (6 157 tonnes excluding EoL emissions over a 30-year period).

*(iv)* *Proposed derogation RO2d: 'refrigerants, clean fire-suppressing agents and insulating gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment placed on the market before 18 months after EiF (or placed on the market after 18 months after EiF based on an applicable derogation).*

A derogation without a time limit is proposed for maintenance and refilling of existing MAC and transport regrigeration. This derogation is a broader derogation, compared to RO2a and RO2b. This derogation proposed to make refilling of all these equipments possible, also after the 5 and 12 years proposed derogation periods in RO2a and RO2b. For the purposes of the impact assessment, it was assumed, based on expert judgement and an average equipment service life of 15 years, that the quantified emissions from refrigeration and MAC would progressively decline to zero (linear function) over the 15 years after the 18-month transitional period and the respective derogation periods as proposed in RO2a and RO2b. Therefore, a derogation for this specific use is estimated to result in additional emissions of 365 486 tonnes compared to RO1 including EoL (295 965 tonnes excluding EoL) emissions over the 30-years assessment period compared to RO1.

*(v) Proposed derogation RO2e: Additives to hydraulic fluids in transport vehicles*

A 12-year derogation is proposed. The proposed derogation will likely cause additional emissions of fluoropolymers and probably PFAAs including PFAA precursors.

There is no specific data available on the additional emissions that would occur from this use-specific derogation although they can be expected to be small as the PFAS use derogated is limited and has only some applications in aviation. The emissions related to hydraulic fluids are assumed to be 0.1 t/year in 2020 (#8857). Therefore, a derogation for this specific use is estimated to result in additional emissions of 1 tonne compared to RO1 including EoL emissions over the 30-years assessment period compared to RO1. There is no difference between the additional emissions with and without EoL emissions associated with this derogation.

### j) Evaluation of environmental impacts of RO2 relating to electronics and semiconductors

*(i) Proposed derogation RO2a: Heat transfer fluid for industrial and professional use of vapor phase soldering for electronics until 13.5 years after EIF.*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible.

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to vapor phase soldering. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 93 tonnes including EoL emissions (and 89 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(ii) Proposed derogation RO2b: Insulation material of electronic components until 13.5 years after EIF (note that this covers both derogations, §6h and 6i)*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible.

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to wires and cables and insulation material of electronic products. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 5708 tonnes including EoL emissions (and 3 246 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(iii) Proposed derogation RO2c: Anti-drip agents in plastics of electronic components until 13.5 years after EIF*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible.

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to anti-drip agents in plastic additives. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 556 tonnes including EoL emissions (and 260 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(iv) Proposed derogation RO2d: Coatings and films on displays and lenses of electronic complex objects until 6.5 years after EIF*

A derogation is proposed for 5 years after the 18-month transition period. Stakeholders indicate that some alternatives are on marked and that new nano-based coatings can be used to replace PFAS, however uncertainties remain for the availability.

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to coating and film of electronic components in film for foldable devices or those unspecified. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 121 tonnes including EoL emissions (and 116 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(v) Proposed derogation RO2e: Coatings and films of electronic components (excluding displays and lenses) until 13.5 years after EIF*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to printed circuit boards, anisotropic conductive film, transducers and sensors, ferroelectric films (actuators and micro) and piezoelectric panels/films (sensors). Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 883 tonnes including EoL emissions (and 623 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(vi) Proposed derogation RO2f: Printed circuit boards and antennas until 13.5 years after EIF*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible.

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to printed circuit boards and antennas and membranes in electronic components soldering. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 31 tonnes including EoL emissions (and 10 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(vii) Proposed derogation RO2g: Photonics until 13.5 years after EIF A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible*

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to photonics. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 36 tonnes including EoL emissions (and 20 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(viii) Proposed derogation RO2h: Heat transfer fluid for 2-phase immersion cooling until 13.5 years after EIF*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible.

The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related heat transfer fluids, immersion cooling and thermal battery systems in heat transfer fluids. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 8 244 tonnes including EoL emissions (and 7 878 tonnes excluding EoL emissions) over the assessment period compared to RO1.

(ix) Proposed derogation RO2i: Semiconductor manufacturing until 13.5 years after EIF

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible nor available for all uses in semiconductor manufacturing.

Based on stakeholder input, only a fraction of the total PFAS used will remain on the semiconductor (1-1.5%), whereas the remainder is emitted trough production or guided toward waste management such as incineration and wastewater treatment. For the use of plasma etching information indicated that around 25% of the PFAS used will be destroyed during the process and therefore not emitted. For all other uses, PFAS used will eventually be emitted either during production, service life or waste (incl. production waste). The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to the manufacturing of semiconductors. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 1 670 tonnes including EoL emissions (and 848 tonnes excluding EoL emissions) over the assessment period compared to RO1.

## k) Evaluation of environmental impacts of RO2 relating to the energy sector

### (i) *Proposed derogation RO2a: Front- and backsheets of photovoltaic cells until 6.5 years after EIF*

A derogation is proposed for 5 years after the 18-month transition period. Alternatives are available on the market. However, significant uncertainties remain on the availability as the vast majority of photovoltaic cells are imported into EU.

Specific data on the additional emissions that would occur from this use-specific derogation is available and they can be expected to be relatively small. For the purposes of the impact assessment, it was assumed, based on expert judgement, that all emissions related to photovoltaic uses in the production, use (service life) phase and EoL phase will continue in the derogation period. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 314 tonnes including EoL emissions (90 tonnes excluding EoL emissions) over the assessment period compared to RO1.

### (ii) *Proposed derogation RO2b: Separator coatings for batteries until 6.5 years after EIF*

A derogation is proposed for 5 years after the 18-month transition period. Alternatives are in development and are, according to stakeholders, likely to be introduced within a 5 year derogation period.

Specific data on the additional emissions that would occur from this use-specific derogation is available and they can be expected to be relatively small. It should be noted that tonnages used for coatings for separators in batteries (and emissions) are included in the overall FP tonnages for batteries. For the purposes of the impact assessment, it was assumed that, based on expert judgement, 5% of the FP tonnages and the emissions in the production phase of batteries in the baseline is used for the coating of separators in batteries is, in which ERC5 is applied. It is assumed that these are mixtures (release factor: 50%), and that these uses and emissions will continue during the derogation period. Moreover, in the use (service-life) phase and waste phase, 5% of the total battery tonnage is allocated for mixtures. We also assume that additional EoL emissions will continue. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 8 827 tonnes including EoL emissions (8 660 tonnes excluding EoL emissions) over the assessment period compared to RO1.

### (iii) *Proposed derogation RO2c: PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers until 6.5 years after EIF*

A derogation is proposed for 5 years after the 18-month transition period. Stakeholders indicate that alternative techniques can be implemented in medium-voltage switchgear. However, uncertainties remain for the application in high voltage switchgear~~s~~.

Specific data on the additional emissions that would occur from this use-specific derogation is available and they can be expected to be relatively small. For the purposes of the impact assessment, it was assumed that, based on expert judgement, 50% of the total PFAS in the use phase will be fully mineralised due to the high temperature of the electrical arc. Therefore, this percentage will not be emitted nor stay in the product. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 19 tonnes including EoL emissions (8 tonnes excluding EoL emissions) over the assessment period compared to RO1.

(iv) *Proposed derogation RO2d: Fuel cells and electrolysers until 13.5 years after EIF*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible.

Specific data on the additional emissions that would occur from this use-specific derogation is available and they can be expected to be relatively small. As the derogation only covers the membrane electrode assemblies (MEA) or similar applications in the fuel cells or electrolysers, a fraction of the emissions related to fuel cells is covered under this derogation. In addition, it is assumed that all emissions related to PEM electrolyser, PEM compressor, purifier and extractor, alkaline water electrolysers and chemical production in production, use (service life) phase and EoL phase will continue. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 970 tonnes including EoL emissions (357 tonnes excluding EoL emissions) over the assessment period compared to RO1.

(v) *Proposed derogation RO2e: Binders and electrolytes in batteries until 13.5 years after EIF*

A derogation is proposed for 12 years after the 18-month transition period. Alternatives are not technically feasible.

Specific data on the additional emissions that would occur from this use-specific derogation is available and they can be expected to be relatively small. It should be noted that tonnages used for coatings of separators in batteries (and associated emissions) are not included in the estimate as they are covered in RO2b. For the purposes of the impact assessment, it was assumed that, based on expert judgement, 95% of the FP tonnages and the emissions in the production phase of batteries is used in articles (excluding coating for separators in batteries) and therefore ERC3 are applied, and these will continue in the derogation period. Moreover, Iin the use (service-life) phase and EoL phase, 95% of the total battery tonnage is allocated for articles. We also assume that 100% of the PFAA precursors tonnages and emissions will continue. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 30 745 tonnes including EoL emissions (20 244 tonnes excluding EoL emissions) over the assessment period compared to RO1.

### l) Evaluation of environmental impacts of RO2 relating to construction products

(i) *Proposed derogation: Polymeric PFAS (fluoropolymers and perfluoropolyethers) used in bridge and building bearing*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. The proposed derogation covers uses related to bridge and building bearings within fluoropolymers and perfluoropolyethers. There is, therefore, **sufficiently strong evidence** that the proposed derogation will cause additional emissions. Additional mean emissions are estimated as 684 t with EoL emissions (445 t without EoL emissions). As a result of the derogation, the effectiveness of the restriction is expected to decrease to 95%.

(i) *Proposed derogation: Polymer additives used for fire safety purposes*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. The proposed derogation covers uses related to and polymer additives used for fire safety purposes within fluoropolymers and perfluoropolyethers. There is, therefore, **sufficiently strong evidence** that the proposed derogation will cause additional emissions. Additional mean emissions are estimated as 96 t with EoL emissions (69 t without EoL emissions). As a result of the derogation, the effectiveness of the restriction is expected to decrease to 96%.

### m) Evaluation of environmental impacts of RO2 relating to lubricants

(i) *Proposed derogation: Industrial and professional uses of lubricants or lubricant additives*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. The proposed derogation covers all uses of PFPEs, PFAAs and their precursors, fluorinated gases, and a large fraction of fluoropolymers. While it is not possible to quantify the precise tonnage and amount of emissions of fluoropolymers (mainly micro-powder PTFE) covered by the derogation, it is assumed that the derogation will cover all PFAS emissions. Assuming that the derogation causes all emissions from PFPEs, PFAAs and their precursors, and fluorinated gases, and of fluoropolymer emissions will continue for 12 years, additional mean emissions can be expected to be about 33 732 t with EoL emissions (32 774 t without EoL). The effectiveness of the RO2 is expected to decrease to 62% with EoL.

### n) Evaluation of environmental impacts of RO2 relating to the petroleum and mining sector

(i) *Proposed derogation: PFAS in gas and oil tracers*

A 12-year derogation is proposed. There is **sufficiently strong evidence** (i.e. based on referenced quantitative data) that a derogation of all PFASs leads to slightly higher emissions compared to a full ban (RO1). Expected emissions under a 12-year derogation are 3.4 t compared to 3.3 t under RO1). The increase of emissions compared to RO1 is 0.2%.

### o) Evaluation of environmental impacts of RO2 relating to the printing applications

*(i) Proposed derogation: Toners*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are the emissions related to the manufacturing, service life (use) and EoL phase of toners. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of around 1 ton including EoL emissions (1.3 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(ii) Proposed derogation: Latex printing inks*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all of the quantified emissions from latex printing inks. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of around 1.2 tonnes including EoL emissions (1.5 tonnes excluding EoL emissions) over the assessment period compared to RO1.

*(iii) Proposed derogation: Electrophotographic press units*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from electrophotographic press units. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 88.9 tonnes including EoL emissions (89.6 tonnes excluding EoL emissions) over the assessment period compared to RO1.

#### *(iv) Proposed derogation: Kinetic printing components*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from kinetic printing components. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 5.7 tonnes including EoL emissions ( 4 tonnes excluding EoL emissions) over the assessment period compared to RO1.

#### *(v) Proposed derogation: Photosensitive materials*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from photosensitive materials. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 3 tonnes including EoL emissions (and 2.9 tonnes excluding EoL emissions) over the assessment period compared to RO1.

#### *(vi) Proposed derogation: Toners for use in existing equipment put on the market until 13.5 years after EiF*

A derogation without a time limit is proposed to allow the continued use of PFASs in toners for use in existing equipment (defined as equipment placed on the market before the end of the derogation period for toners). Whilst the derogation is open-ended in duration, in practice, the quantities derogated will progressively decline to zero as equipment that was placed on the market/installed prior to the end of the derogation period reaches the end of its service life and is replaced (assumingly after 7 years).

The additional emissions that would be associated with this use-specific derogation are assumed to be all emissions from toners. These emissions are assumed to progressively decline to zero (linear function) over the 7 years after the derogation period. Therefore, a derogation for this specific use is estimated to result in additional emissions of 3.4 tonnes including (and 3.2 excluding EoL emissions) over the assessment period compared to RO1.

#### *(vii) Proposed derogation: Latex printing inks for use in existing equipment put on the market until 13.5 years after EiF*

A derogation without a time limit is proposed to allow the continued use of PFASs in latex printing inks for use in existing equipment (defined as equipment placed on the market before the end of the derogation period for latex printing inks, i.e. equipment placed on the market until 13.5 years after EiF). Whilst the derogation is open-ended in duration, in practice, the quantities derogated will progressively decline to zero as equipment that was placed on the market/installed prior to the end of the derogation period reaches the end of its service life and is replaced (assumingly after 7 years).

The additional emissions that would be associated with this use-specific derogation are assumed to be the emissions from latex printing inks. These emissions are assumed to progressively decline to zero (linear function) over the 7 years after the derogation period. Therefore, a derogation for this specific use is estimated to result in additional emissions of around 3.4 tonnes including EoL emissions (and around 3.2 tonnes excluding EoL emissions) over the assessment period compared to RO1.

### p) Evaluation of environmental impacts of RO2 relating to sealing applications

#### *(i) Proposed derogation: Sealing applications in industrial uses*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all the quantified emissions in the baseline situation. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of around 8 758 tonnes including and 6 842 tonnes excluding EoL emissions over the assessment period compared to RO1. As a result of the derogation, the effectiveness of the restriction is expected to decrease to 66% over the assessment period.

## q) Evaluation of environmental impacts of RO2 relating to machinery applications

### *(i) Proposed derogation: Machinery applications in industrial uses*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all the quantified emissions in the baseline situation. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of around 381 tonnes including and 309 tonnes excluding EoL emissions over the assessment period compared to RO1. As a result of the derogation, the effectiveness of the restriction is expected to decrease to 66% over the assessment period.

## r) Evaluation of environmental impacts of RO2 relating to other medical applications

### *(i) Proposed derogation RO2a: Propellants in pMDIs*

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional Fluorinated gases emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from PCTFE in medicinal packaging (blisters). Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 13 740 tonnes including EoL emissions (over the assessment period compared to RO1).

### *(ii) Proposed derogation RO2b: Blisters for solid oral dose formulations*

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from Propellants in pMDIs. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 16 tonnes including EoL emissions (over the assessment period compared to RO1).

### *(iii) Proposed derogation RO2c: Excipients in medicinal products for ophthalmic and dermatological therapies*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs and PFAA precursors emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from SFAs as excipients. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 0.4 tonnes including EoL emissions (over the assessment period compared to RO1).

### *(iv) Proposed derogation RO2d: Coating in release liners and backing film in transdermal patches*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from Fluoropolymer-coated release liners in transdermal patches. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 0.001 tonnes including EoL emissions (over the assessment period compared to RO1).

*(v) Proposed derogation RO2e: Coated rubber stoppers in vials/flasks for injectable medicinal products*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from Fluoropolymer-coating (PTFE/ETFE) on rubber stoppers for vials. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 1 ton including EoL emissions (over the assessment period compared to RO1).

*(vi) Proposed derogation RO2f: Coated canisters in pressurized metered-dose inhalers (pMDIs)*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from Fluoropolymer-coated (FEP/PFA) canisters in pMDIs. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 0.1 tonnes including EoL emissions (over the assessment period compared to RO1).

*(vii) Proposed derogation RO2g: Coated plungers in pre-filled syringes*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 50% of the emissions from Fluoropolymer-coating (PTFE/ETFE) on plungers in pre-filled syringes and in pre-filled injection pens & autoinjectors. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 0.5 tonnes including EoL emissions (over the assessment period compared to RO1).

*(viii) Proposed derogation RO2h: Pre-filled injection pens & autoinjectors*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 50% of the emissions from Fluoropolymer-coating (PTFE/ETFE) on plungers in pre-filled syringes and in pre-filled injection pens & autoinjectors. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 0.5 tonnes including EoL emissions (over the assessment period compared to RO1).

### s) Evaluation of environmental impacts of RO2 relating to military applications

*i. Proposed derogation: Military applications*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all the quantified emissions in the baseline situation. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of around 17 372 tonnes including and 9 557 tonnes excluding EoL emissions over the assessment period compared to RO1. As a result of the derogation, the effectiveness of the restriction is expected to decrease to 72% over the assessment period.

### t) Evaluation of environmental impacts of RO2 relating to explosives in civil applications

*i. Proposed derogation: Explosives used in military applications*

A derogation is proposed for 12 years after the 18-month transition period. The additional emissions that would occur from this use-specific derogation are assumed to be all the quantified emissions related to military applications. These include coating of ammunition, large calibre ammunition (including pyrotechnic illumination devices, tank ammunition), pyrotechnic composition such as oxidants, coatings and binder as a substance or mixture which produces an "effect" by heat, light, gas/smoke or a combination of the above and surface treatment/coating (including coating of processing tools for energetic materials production). Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of around 22 tonnes over the assessment period compared to RO1. As a result of the derogation, the effectiveness of the restriction is expected to decrease to 95% over the assessment period.

## u) Evaluation of environmental impacts of RO2 relating to technical textiles

*(i) Proposed derogation RO2a: Woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 40% of the emissions from medical applications in technical textiles. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 1 420 tonnes including and excluding EoL emissions over the assessment period compared to RO1.

*(ii) Proposed derogation RO2b: Technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay*

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 50% of the emissions from technical textiles in transport vehicles. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 289 tonnes including EoL emissions (275 tonnes excluding EoL) over the assessment period compared to RO1.

*(iii) Proposed derogation RO2c: Technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 50% of the emissions from technical textiles in transport vehicles. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 850 tonnes including EoL emissions (808 tonnes excluding EoL) over the assessment period compared to RO1.

*(iv) Proposed derogation RO2d: Industrial use of fluoropolymers in filtration and separation media for water treatment and purification*

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions from fluoropolymers related to filtration and separation media used for water and water treatment. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 2 026 tonnes including EoL emissions (1 998 tonnes excluding EoL) over the assessment period compared to RO1.

*(v) Proposed derogation RO2e: HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases excluding general (HVAC) ventilation*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs and polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be all of the emissions related to air and gas filtration. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 2 959 tonnes including EoL emissions (2 906 tonnes excluding EoL) over the assessment period compared to RO1.

*(vi) Proposed derogation RO2f: Sound-permeable and vent filters for electrical and electronic equipment*

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs and polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 25% of the emissions from other uses of filtration and separation media. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 101 tonnes including EoL emissions (67 tonnes excluding EoL) over the assessment period compared to RO1.

*(vii) Proposed derogation RO2g: Oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs and polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 25% of the emissions from other uses of filtration and separation media. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 296 tonnes including EoL emissions (196 tonnes excluding EoL) over the assessment period compared to RO1.

*(viii) Proposed derogation RO2h: Industrial use as media in liquid-liquid separation*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs and polymeric PFAS emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 25% of the emissions from other uses of filtration and separation media. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 296 tonnes including EoL emissions (196 tonnes excluding EoL) over the assessment period compared to RO1

### v) Evaluation of environmental impacts of RO2 relating to broader industrial uses

*(i) Proposed derogation RO2a: Solvents and precision cleaning*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional fluorinated gases emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 100% of the emissions from solvents and precision cleaning agents, including aerospace and defense. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 2 651 tonnes including EoL emissions (2 634 excluding EoL emissions) over the assessment period compared to RO1.

*(ii) Proposed derogation RO2b: Catalysts and processing aids*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 100% of the emissions from catalysts and processing aids, excluding ionic liquids. Therefore, a 12-year derogation for this specific use is estimated to result in additional emissions of 15 tonnes including and excluding EoL emissions over the assessment period compared to RO1.

*(iii) Proposed derogation RO2c: Catalysts and processing aids*

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18-month transition period. Compared to a ban (RO1), a derogation will cause additional PFAAs emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 100% of the emissions from catalysts and processing aids, including chain transfer agents and ionic liquids. Therefore, a 5-year derogation for this specific use is estimated to result in additional emissions of 6 tonnes including EoL emissions (5 tonnes excluding EoL) over the assessment period compared to RO1.

### w) Evaluation of environmental impacts of RO3 relating to manufacturing

Proposed derogation RO3b: Manufacture of PFAS with or without the use of fluorinated polymerisation aids in the production of polymeric PFAS under controlled conditions with average emission factors (= Annual emission of PFAS / total annual amount of PFAS manufactured on site) not exceeding:

i. 0.0090% to air, 0.0010% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing until end of 2030;

ii. 0.0030% to air, 0.0006% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing from end of 2030 onwards;

iii. 0.01% to all compartments for all PFAS emissions not mentioned above from sites manufacturing polymeric and non-polymeric PFAS 6.5 years after EiF.

The derogation is proposed for a time-unlimited period. Compared to a ban (RO1), a derogation will cause additional emissions. The additional emissions that would occur from this use-specific derogation are assumed to be 100% of the emissions from all uses related to manufacturing. Limit values assume emission factors not higher than 0.01% 6.5 years after EiF for emissions from PFAS manufacturing not related to polymerization aid technology in fluoropolymer manufacturing. For emissions related to polymerization aid technology in fluoropolymer manufacturing, the Dossier Submitter assumes a limit value of 0.01% during 2024-2030 (0.009% air, 0.001% water), and of 0.0036% after 2030 (0.003% air, 0.0006% water). Therefore, a time-unlimited derogation for manufacture is estimated to result in additional emissions of 3 471 tonnes including EoL emissions (3 459 tonnes excluding EoL) over the assessment period (2025-2055) compared to RO1.

### 2.4.4. **Proportionality to the risk**

Evaluating the proportionality of restriction options requires to assess whether:

- The restriction options are targeted to the identified risk and do not inadvertently affect users or actors in the supply chain which are not associated with the identified risk (effectiveness);
- The efforts needed from the actors to implement and from the authorities to enforce the restriction options correspond in amount or degree to the adverse effects that are being avoided; and
- Restriction options ensure a good balance between costs and benefits and are cost-effective (ECHA, 2007).

The standard approach adopted to assess proportionality of PBT/vPvB chemicals is a cost-effectiveness analysis (CEA), assuming that cost-benefit analysis cannot be used due to a lack of safe concentration levels of PBT/vPvB chemicals (ECHA, 2016). Moreover, for assessing the effectiveness of restriction options the expected emission reduction is used as a proxy. As discussed in section 1.1.6, emissions represent the pollution inflow into the environment. They do, however, not reflect the accumulation of pollution over time as a result of the persistence of PFASs, indicating the long-term environmental impact potential of PFASs (Gabbert et al., 2022).

Socio-economic costs of PFAS emissions to the environment are considerable and are growing with prolonged PFAS use. Continued PFAS use has a broad range of societal effects, with an unclear or indicative price tag. Available evidence on the main types of societal costs associated with PFAS emissions and the resulting accumulation and exposure to these substances is summarised in the following for illustration purposes to exemplify the magnitude of societal costs that might be avoided by a restriction. It nevertheless needs to be noted that complete monetarization of benefits is not possible for the reasons described in the preceding paragraph and the inability to quantify human health impacts (described in section 2.4.2). The European Commission (DG Environment) has commissioned a study[44] on the cost of PFAS pollution for society, which is expected to yield additional insight into the potential monetary benefits of reducing PFAS exposure. At the time of writing, the results of this study were not yet available.

#### Health costs

There are potentially significant benefits in terms of reduced health costs associated with restricting PFAS use and subsequent emissions to the environment. A lower reduction of emissions will likely lead to increased health impacts, as well as to higher costs for society, e.g. due to increased healthcare costs (Obsekov et al., 2022). Costs to society of health harm linked to PFAS exposure have been estimated to be between €52 billion and €84 billion a year in the EEA (Goldenman et al. (2019); stakeholder comment IDs #9038, 9583 and 9477). This estimate covered costs associated with kidney cancer, all cause mortality and hypertension due to workplace exposure, exposure of communities in proximity to PFAS production or manufacturing sites or with PFAS in their drinking water due to the use of firefighting foams, and exposure of the general population from food, consumer goods and via the environment. According to the Global PFAS Science Panel (comment ID #9038) this could be an underestimate due to the more limited knowledge about PFAS health effects and PFAS

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[44] https://trinomics.eu/project/the-cost-of-pfas-pollution-for-our-society/, date of access: 2025-05-27.

exposure at the time of the study. The Global PFAS Science Panel notes that the evidence on links between PFAS and other diseases has increased, and that other costs of living with a disease such as health care costs, reduced productivity, and lower quality of life were not covered by the estimates. A 2022 study (Obsekov et al., 2022) on US health-related costs found a similar range of annual costs on a per capita basis[45] as the previously mentioned estimates from Goldenman et al. (2019), but covered more disease endpoints, and focused on routine low-level environmental PFAS exposure. That study may reflect healthcare costs that differ from those in the EU. The Global PFAS Science Panel highlights that additional costs not yet quantified by these or other studies include health and social concerns in communities affected by PFAS contamination, as well as burdens on governments for monitoring contamination, monitoring health impacts, and addressing citizens' health concerns (comment ID #9038).

**Environmental costs**

Although the specific scale and nature of environmental effects from PFASs is difficult to determine, and research on the impacts of PFASs on ecosystem services[46] is currently lacking, there could also be potentially significant benefits from reducing PFAS emissions in terms of reduced ecosystem service impacts. As discussed in sections 1.1.4 and 1.1.6, due to the persistence of PFASs in combination with identified and possible other concerns, continued PFAS exposure has the potential to disrupt ecosystem functioning. This could lead to economic costs in terms of lost ecosystem services. Due to significant uncertainties and data gaps associated with the environmental effects of PFAS, existing monetary estimates of the societal costs of PFAS pollution have focused on health costs and the costs for cleaning up PFAS pollution (e.g. Goldenman et al. (2019)). However, in some cases the loss of natural resources whose use is prevented by PFAS contamination can also be clearly identified. Both clean-up costs (remediation and purification) and the loss of natural resources are discussed further below.

**Remediation and purification costs**Because of historical, and out of scope of this restriction proposal, environmental contamination of PFASs in soils and water sheds, remediation and purification costs are currently incurred across Europe. Several stakeholders highlighted significant and increasing costs for assessing, remediating, treating and destroying PFAS contamination in soils, water, waste and biota in the consultation on the Annex XV report (e.g. comment IDs #7146, 7871, 8385, 8863, 9367, 9477, 9561). Affected areas include PFAS production locations and large airports that used PFAS-containing firefighting foams, industrial sites where PFASs are used, or where PFAS-contaminated material was used. The costs associated with the remediation of contaminated soils due to PFAS-containing firefighting foams alone have been estimated to range from hundreds of millions to billions of € if such use would be allowed to continue in the future (ECHA, 2022). Around PFAS production sites soils can be contaminated with PFASs leading to significant remediation cost. In Belgium, 3M recently signed a remediation agreement of €571 million

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[45] The total costs were estimated to be $37-59 billion, which is equivalent to about €33-53 billion (assuming an exchange rate of 0.9), or about €102-163 per capita (assuming a population of 325 million in the USA). For comparison, the per capita cost of Goldenman et al, 2019 would be around €100-161 (assuming a population of 522 million in the EEA).

[46] The benefits humans obtain from ecosystems. Examples of relevant services are the provision of food, water, etc., climate regulation and cultural services such as recreation.

with the Flemish government for PFAS-related remedial actions around their PFAS production facility in Zwijndrecht[47]. In addition, PFAS-contaminated soils have led to delays in infrastructure and building projects in the Netherlands and Belgium, leading to increased costs for society. Stakeholder input to the consultation on the Annex XV report (comment IDs #8274, 9367) also highlighted a case in Germany, where application of paper sludge mixed with compost on arable land has led to the contamination of 1 100 hectares of soil in Central Baden and the groundwater from Rastatt to Ottersweier. Comprehensive remediation is unfeasible, and the state, the district, the municipalities, the water suppliers and the agriculture industry have spent mid-double-digit millions to protect the population since 2013, with further costs expected for decades to come.

In 2019, costs for "non-health" impacts of PFAS pollution were estimated to be €821 million to €170.8 billion over a 20-year period in the EEA (Goldenman et al. (2019)); cited by stakeholder response #9137). The estimates assumed that between 1% and 10% of Europe's overall population (best estimate at 3%) were affected, and covered costs of PFAS monitoring, health assessments, temporary provision of uncontaminated drinking water, upgrading water treatment, and soil remediation. This is likely an underestimate according to the Global PFAS Science Panel (comment ID #9137). More recently, the Forever Pollution Project identified nearly 23 000 sites in Europe contaminated with PFAS above 10 nanograms per litre according to environmental samples, and an additional 21 500 sites in Europe are suspected of being contaminated based on past and present industrial activity (Horel, 2023). Using the Forever Pollution Project's data, it was estimated that removing all current and future PFAS releases through soil remediation, drinking water treatment, wastewater treatment and landfill leachate treatment would cost €2 trillion over a period of 20 years (Ling A., 2025). It is therefore plausible that high costs would be incurred in the future under the baseline scenario with continued production and use of the PFASs in scope in Europe due to new needs for soil remediation or clean-up (if remediation or clean–up is even possible at all).

### Loss of natural resources

PFAS contamination also has the potential to prevent the use of natural resources for various purposes, including drinking water, nutrients and food.

Drinking water

Several stakeholders noted increasing concerns about PFAS driving drinking water treatment costs and threatening safe drinking water supply in the consultation on the Annex XV report (e.g., #6185, #7146, #7331, #7642, #8385, #9367, #9561, #9583). PFASs are detected in drinking water around Europe (see 1.1.5.7). In the Netherlands, PFASs in drinking water produced from surface water (river) are already above acceptable concentrations considering health-based guidance values and exposure to PFASs from other sources (food and environment)[48]. More generally, according to EurEau (2025) most surface water bodies have PFAS concentration levels that require additional treatment before the water is safe for drinking. In groundwater, known PFAS contamination is still low and only minimal treatment is required for drinking, but an increasing number of shallower groundwater bodies is expected to exceed proposed European and national drinking water quality standards if PFAS releases are not drastically reduced (EurEau, 2020).

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[47] https://news.3m.com/2022-07-06-Agreement-Reached-Between-the-Flemish-Government-and-3M-Belgium-to-Support-the-People-of-Flanders, date of access: 2023-01-06.

[48] https://www.rivm.nl/en/news/pfas-levels-in-drinking-water-from-river-water-need-to-be-brought-down, date of access: 2023-01-06.

Due to their properties, most PFASs are difficult to remove from drinking water with current techniques in a manner which would be feasible for normal drinking water purification facilities. According to the Dutch Province Gelderland (comment ID #9561), drinking water companies in the Netherlands point to the inability to completely remove PFAS during drinking water treatment. Commonly available drinking water treatment technologies remove longer chain molecules with a significant resource and climate footprint, and the removal of short and ultrashort chain PFASs requires more advanced technologies with even higher costs and energy consumption, which also require 20% more abstracted water and create a waste brine that is very difficult to dispose of (EurEau (2025); stakeholder responses #7642, 8385, 9367).

Continued use and subsequent emissions of PFASs into the environment will increase the share of drinking water inlets that need additional purification efforts to filter out PFASs at significant costs. The European representation of drinking water and waste water operators (EurEau) are particularly concerned about the affordability of water services with increased costs for water purification due to PFAS contamination (EurEau, 2020). For example, in Italy, the local water supply company Acque del Chiampo S.p.A. invested over €20 million on purification and remediation due to large scale PFAS contamination in the Veneto Region affecting groundwater, surface water, drinking water and land. One of the sources of the contamination has been a fluorochemicals production plant (EurEau, 2020). One stakeholder (comment ID #9583) reports estimated costs of $42.5 million (around €38 million[49]) over 2022-2030 for PFAS drinking water purification by retrofitting individual houses with water filters in Maine, United States.

Recovery and use of nutrients and materials

Several stakeholders (comment ID #7146, 9137, 9161, 9583) also highlighted the negative impact of PFASs in products on circular economy ambitions, notably PFAS contamination preventing the use of contaminated wastewater, sewage sludge and soil. For example, EurEau and the German Technical and Scientific Association for Gas and Water report that PFASs jeopardise nutrient and material recovery from wastewater and sewage sludge (comment ID #7828, 9367). Since PFASs cannot currently be reliably removed from wastewater and sewage sludge, PFASs could prevent the increasingly important uses of highly treated wastewater for farmland irrigation and of sewage sludge for land reclamation, which could negatively affect food security (EurEau (2025); consultation response #7828). Sewage sludge application to farmland to increase its phosphorus, nitrogen and carbon content can benefit farmers in the order of €50-60 per hectare per year, or €60-70 per tonne of dry matter sludge per year (according to one estimate from Sweden from 2018, cited in stakeholder response #7828). If the PFAS content in sludge exceeds regulatory safety limits, the agricultural benefit is lost, but also costly alternative sludge management routes need to be developed (comment ID #7828, 9367). EurEau (comment ID #7828) concludes that the restriction would yield significant benefits to the water sector through avoided costs for drinking water treatment, wastewater treatment, and alternative sewage sludge management routes, even though these costs cannot currently be quantified for the whole of Europe.

Besides agricultural use, according to one stakeholder (comment ID #9561), PFAS contamination in soil can also prevent its use in housing construction.

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[49] Assuming an exchange rate of 0.9.

Food production

Several stakeholders have noted increasing concerns about PFAS affecting food production (e.g. comment ID #7146, 7871, 9561, 9583). For example, PFAS contaminated surface waters leads to a decrease in fishing grounds as consumption of fish, shellfish and crustaceans from these waters can lead to exceedance of the health-based guidance value for PFASs. To date, recreational and professional fishing in parts of the Dutch Western Scheldt is advised against by the Dutch Fishermen's Association due to the high PFAS concentrations leading to additional costs for the fishing industry. One stakeholder (comment ID #9561) reports government advisories against consuming food from gardens near a PFAS manufacturing site in Dordrecht, and against eating fish caught at several locations in the Netherlands. Another stakeholder (comment ID #7871) reports that PFAS wildlife monitoring carried out by Hessian authorities in Germany has shown that ubiquitous exposure to PFAS prevents the safe consumption of regional wildlife, in particular wild boar and freshwater fish. Moreover, bioaccumulation of PFAS in farm animals can lead to exceedances of limit values for PFASs in food (BfR, 2024) and therefore lead to economic losses for farmers (comment ID #9583).

**Other costs**

Some stakeholders (e.g. comment ID #9137, 9561) note that there may be other non-health societal costs of PFAS pollution which could be reduced by the restriction, but which have not yet been quantified, such as for example costs from loss of property value in polluted areas, some fluorinated gases' contribution to global warming, and inhibiting recreation. For example, authorities have advised against swimming at certain sites or playing with sea foam due to PFAS pollution in the Netherlands and Belgium (EurEau (2025); stakeholder response #9561).

#### 2.4.4.1. Comparison of different restriction options

Applying CEA requires quantitative data on the expected costs and the expected emission reduction of each restriction option considered. As illustrated by Table 10 and Table 11, this quantitative information on costs is only available in very few cases. As such, a ranking of restriction options based on cost-effectiveness is not possible in most cases. Cost-effectiveness and proportionality are thus assessed in a qualitative manner. To propose the most appropriate RO, the Dossier Submitters compare the level of costs and the effectiveness of the restriction options. The Dossier Submitters provide information on the differences between RO1 and RO2 with respect to the extent of emission reduction (used as proxy for the benefits of different restriction options) and costs. The Dossier Submitters make use of gradation scales to evaluate effectiveness (i.e. total emissions avoided at sector level) and costs. These two graduation scales reveal a matrix, which allows evaluating the likelihood that a restriction option can be considered proportionate, and to compare restriction options with each other (for more information about the approach used to assess proportionality see section E.2 in Annex E). The conclusions about proportionality are included in Table 15.

**Table 15. Comparison of RO1 and RO2.**

| **Use** | **Derogations under RO2** | **Cost and other impacts of RO2 (in comparison to RO1)** | **Environmental impact of RO2 (in comparison to RO1)** | **Other aspects** | **Overall evaluation of proportionality** |
|---|---|---|---|---|---|
| **TULAC (Annex E.2.2.)** | | | | | |
| Includes:<br>• Home textiles<br>• Consumer apparel<br>• Professional apparel and PPE<br>• Leather<br>• Home fabric treatments (sprays)<br><br>Fluoropolymers account for the majority of the use of PFASs in TULAC. | **12-year** derogation after the transition period **proposed** for:<br>• Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I<br>• Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers<br>• Impregnation agents for re-impregnating of articles referred to above | There is sufficiently strong evidence that the substitution potential is low for PPE at EiF. The added time offered by the 12-year derogation provides opportunities to develop and implement alternatives, reducing both producer surplus losses for manufacturers of PPE and producer surplus losses in the wider supply chain and welfare losses for end-users (resulting from the absence of sufficiently protective PPE, which would also have a reduced service life duration) due to no technically feasible alternatives being known and costs resulting from earlier disposal of PPE as a result of the unavailability of impregnation agents. In addition, employment losses are expected to be significantly reduced under RO2 with information from the consultation on the Annex XV report suggesting that at least 26 702 jobs would be at risk in the five sub-sectors under RO1, with over 95% of those being related to the professional apparel and PPE industry. | The derogation covers mainly fluoropolymers and further PFPEs. RO2 achieves a total PFAS emission reduction with EoL of about 627 490 t compared to the baseline. The derogation can, therefore, be expected to reduce the effectiveness of the restriction to about 95%. The extra emissions of RO2 compared with RO1 are estimated to be 6 787 t over 30 years. | | |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | According to information from the consultation on the Annex XV report, annual costs of around €4 017 billion (accounting for lost profits and employment impacts) could be avoided under RO2.<br><br>Conclusion: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | | | |
| **Food contact materials and packaging (Annex E.2.3.)** | | | | | |
| Includes:<br>• Non-stick surfaces in consumer cookware and domestic appliances<br>• Non-stick coatings in industrial and professional bakeware<br>• Paper & board packaging<br>• Polymer processing aids used in flexible plastic film extrusion (for food and non-food applications)<br>• Packaging uses of F-HDPE (fluorinated high density polyethylene)<br>• Other packaging applications | **5-year** derogation after the transition period **proposed** for:<br>• Non-stick coatings in industrial and professional bakeware<br><br>**5-year** derogation after the transition period **proposed** for:<br>• Polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) | Whilst non-stick coatings made from alternatives are widely accepted in the domestic market for professional food and feed production companies within the sector need time for performance of R&D targeted at implementing alternatives that are technically and economically feasible for some product lines. A 5-year derogation for use of PFASs in non-stick coatings in the industrial and professional food and feed production would provide opportunity for businesses to gradually switch away from PFAS coatings, including the companies (largely SMEs) involved in recoating bakeware. The | **Estimated** additional emissions for the two specific derogations over the 5 year derogation period compared to RO1 are 345 t (419 t including end of life emissions) In relation to this reference scenario, additional emissions of the proposed derogation are considered to be small. | | Potentially substantial additional emissions in exchange for:<br>• Reduced producer surplus losses for companies involved in the manufacture of non-stick coating materials and other equipment for the industrial and professional food and feed production and associated reduced consumer surplus losses |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | Dossier Submitters consider that this provides sufficient time to limit inevitable producer surplus losses linked to a switch to the use of alternatives.<br>For PPAs, sufficiently strong evidence was brought forward indicating a lack of alternatives at EiF Several stakeholders considered that it would be possible to develop alternatives if they were granted a 5-year derogation. They would still incur R&D and other costs for implementing alternatives but producer losses would be significantly reduced compared to RO1. | | | |
| **Metal plating and manufacture of metal products (Annex E.2.4.)** | | | | | |
| Includes:<br>• Hard chrome plating<br>• Decorative plating with chrome, plating on plastics and plating with metals other than chrome<br>• Manufacture of metal products not addressed elsewhere | **5-year** derogation after the transition period **proposed** for:<br>• Hard chrome plating | For the hard chrome plating sector there is sufficiently strong evidence of difficulty in transitioning from PFASs. No alternatives will be available by EiF. Added time offered by the derogation provides opportunity to develop and implement alternatives, reducing both potential producer and consumer losses.<br>For all other uses, costs in case of RO2 are either low at most or the evidence is | It is estimated that RO1 would reduce emissions by 94% (946 t without EoL emissions and 948 t with EoL emissions), over the 30-year period 2025 to 2055). The expected additional emissions of RO2, compared to RO1, are 49 t (without and with EoL emissions). This corresponds to an effectiveness of the restriction of 91%. | Since fluoropolymers are not used for hard chrome plating, there is no difference between RO1 and RO2 concerning fluoropolymers. | RO1 is likely not proportionate due to high to very high expected costs. Likely reduction of producer and consumer losses and the risk of job losses.<br>RO2 is likely proportionate as a result of the low to moderate costs. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | too weak to draw conclusions on the magnitude.<br>Conclusion: Costs for the hard chrome plating sector will decrease from High-Very high in RO1 to Low-Moderate in RO2. For the other uses, no differences in costs are expected. | | | |
| **Consumer mixtures and miscellaneous consumer articles (Annex E.2.5.)** | | | | | |
| Includes: Consumer mixtures (all uses) (Fluoropolymers potentially account for small share of use)<br>Miscellaneous consumer articles (Use of fluoropolymers) | No derogations proposed | Not applicable. | Not applicable. | Not applicable. | Impacts of RO2 are equal to RO1, as no derogations are proposed, and RO1 is deemed proportionate |
| **Cosmetics (Annex E.2.6.)** | | | | | |
| Cosmetic products<br>Some use of fluoropolymers in cosmetic products. | No derogations proposed | Not applicable. | Not applicable. | Not applicable. | Impacts of RO2 are equal to RO1, as no derogations are proposed, and RO1 is deemed proportionate |
| Peptide synthesis for cosmetic applications<br>No reported use of fluoropolymers in peptide synthesis. | No derogations proposed | Not applicable. | Not applicable. | Not applicable. | Impacts of RO2 are equal to RO1<br>Proportionality will be evaluated in the next version of the Background Document, when the results of the EIA are available. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| **Ski wax (Annex E.2.7.)** | | | | | |
| Sector as a whole<br>Use of fluoropolymers in relation to ski wax is minor. | No derogations proposed | Not applicable. | Not applicable. | Not applicable. | Impacts of RO2 are equal to RO1, as no derogations are proposed, and RO1 is deemed proportionate |
| **Applications of fluorinated gases (Annex E.2.8.)**<br>*Note that mobile air conditioning (MAC) and transport refrigeration are covered under Transport below* | | | | | |
| Includes:<br>• Refrigeration<br>• Air conditioning and heat pumps<br>• Foam blowing agents<br>• Propellants<br>• Cover gases<br>• Clean fire suppressants<br>• Preservation of cultural paper-based materials<br>• Insulating gas in electrical equipment | **5-year** derogation after the transition period **proposed** for:<br>• Refrigerants in low temperature refrigeration below -50 °C<br>• Insulating gases in high-voltage switchgear (above 145 kV)<br>**12-year** derogation after the transition period **proposed** for:<br>• Refrigerants in laboratory test and measurement equipment<br>• Refrigerants in refrigerated centrifuges<br>• Foam blowing agents in thermal insulation foam<br>• Propellants for technical aerosols | There is sufficiently strong evidence that the substitution potential is low at EiF for several applications. This includes amongst others several specific applications of refrigerants, several applications of foam blowing agents and propellants, as well as some specific applications of clean fire suppressants.<br>In addition, there are no drop-in alternatives for use in existing equipment, e.g. the use of fluorinated gases in refrigeration and switchgear equipment.<br>The added time offered by the 12-year derogations provides opportunities to develop and implement alternatives, reducing both impacts on manufacturers, such as producer surplus | It is estimated that RO1 would reduce emissions across all uses of fluorinated gases by 95% (with and without EoL emissions). Emissions of PFASs to the environment would be reduced by 1 718 883 t over the 30 -year assessment period (2025-2055) (1 407 880 t without EoL emissions).<br>Under RO2, emissions of PFASs to the environment would be reduced by 1 498 108 t over the 30-year assessment period (2025-2055) (1 187 767 t without EoL emissions).<br>This corresponds to an effectiveness of the proposed restriction | n/a | RO2 is found to be a more proportionate restriction option than RO1. Due to the associated low costs and a moderate effectiveness, RO2 is deemed to be likely proportionate. RO1 is, in contrast, deemed to be a restriction option that is likely not proportionate due to the very high costs associated with this restriction option. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | for applications where non-flammability and high technical performance of spray quality are required. The derogation does not apply to products intended for entertainment and decorative purposes for the general public.<br>• Fluorinated gases used as clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health<br>• Preservation of cultural-paper based materials<br><br>A **time-unlimited** derogation after the transition period proposed for:<br>• Refrigerants in HVACR-equipment in buildings where national safety standards and building codes | losses, and impacts on end-users if suitable alternatives are identified. An example of avoided impacts on end-users are the avoidance of increased energy costs associated with the lower insulation performance of foams produced with alternative foam blowing agents.<br><br>In relation to the 5-year derogations, stakeholder feedback suggests that there is some potential for alternatives to be feasible for low temperature refrigeration after a 5-year derogation. A 5-year derogation would thus reduce the impacts on producers associated with this use, whilst maintaining production rates and quality. It would also likely limit the impacts on end-users and avoid the adverse impacts on wider society in relation to healthcare services.<br><br>In relation to insulating gas in high-voltage switchgear, the additional time provides manufacturers and downstream users the opportunity to substitute instead of ceasing operation | option of 83% (80% without EoL emissions). The effectiveness of the restriction option is thus reduced considerably as a a result of the derogations.<br><br>The expected additional emissions of RO2, compared to RO1, are 220 113 t (without EoL emissions) and 220 776 t (with EoL emissions). | | |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | prohibit the use of alternatives<br>- Refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months after EiF<br>A potential derogation for consideration is included for:<br>- [Use of fluorinated gases at the CERN research installation] | thereby limiting impacts on manufactures, e.g. producer surplus losses, and customers. This is the case as<br>information provided by stakeholders suggests that high-voltage electricity products up to 420 kV may start to be replaced with non-PFAS alternatives by 2026. A 5-year derogation is deemed to be sufficient to enable the transition.<br>The time-unlimited derogations also allow for the avoidance of costs: The time-unlimited derogation for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment will, for example, prevent costs related to the premature redundancy of relevant equipment.<br>Conclusion: Costs are therefore expected to decrease from very high costs under RO1 to low costs under RO2. | | | |
| **Medical devices (Annex E.2.9.)** | | | | | |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| Includes:<br>- Implantable medical devices (including medical implants and meshes)<br>- Wound treatment products (non-implantable/non-invasive medical devices)<br>- Tubes and catheters (invasive medical devices)<br>- Other coating applications (non implantable medical devices)<br>- Sterilisation gases<br>- Vision applications (invasive medical devices)<br>- Packaging of medical devices (including PCTFE-based packaging and flexible packaging using PPAs for medical devices) | **12-year** derogation after the transition period **proposed** for:<br>- (i) Implantable medical devices (including medical implants and meshes)<br>- (i) invasive medical devices (e.g. tubes and catheters<br>- (iii) packaging of medical devices | Public health concerns (and their related socio-economic costs) due to reduced functionality of implantable medical devices, invasive medical devices and vision applications are the main socio-economic costs.<br>The information is uncertain on the cost impact of no derogation for wound treatment products coating of medical devices applications. | It is estimated that RO1 would reduce emissions across all uses of medical devices by 97% (with and without EoL emissions). Emissions of PFASs to the environment would be reduced by 376 454 t over the 30 -year assessment period (2025-2055) (371 938 t without EoL emissions).<br>The effectiveness of RO2 is estimated to be 97% (with and without EoL emissions). Emissions of PFAS to the environment would be reduced by 375 657 t over the 30-year assessment period (2025-2055) (371 287 without EoL emissions).<br>The expected additional emissions of RO2, compared to RO1, are 952 t (without EoL emissions) and 797 t (with EoL emissions). |  | RO2 is found to be a more proportionate restriction option than RO1as it would result in<br>- Lower socio-economic costs related to public health effects, as a result of reduced functionality of invasive medical devices, implantable medical devices and vision applications.<br>- Avoidance of high socio-economic costs in applications where packaging is vital for functionality and safety, and where there are no available alternatives that meets the technical requirements. |
| **Transport (Annex E.2.10.)** |  |  |  |  |  |

| **Use** | **Derogations under RO2** | **Cost and other impacts of RO2 (in comparison to RO1)** | **Environmental impact of RO2 (in comparison to RO1)** | **Other aspects** | **Overall evaluation of proportionality** |
|---|---|---|---|---|---|
| Includes:<br>• Uses of fluoropolymers and perfluoropolyethers in transport vehicles[50](excluding ‘sealing applications’, batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles)<br>• Reflective coatings for traffic signs<br>• Additives to hydraulic fluids in transport vehicles<br>• Devices for motion control solutions<br>• Mobile Air Conditioning (MAC) and heat pump systems<br>• Transport refrigeration | **5-year** derogation after the transition period **proposed** for:<br>• Refrigerants in mobile air conditioning and heat pump systems in light duty electrical vehicles<br>• Refrigerants in transport refrigeration other than in marine applications<br><br>**12-year** derogation after the transition period **proposed** for:<br>• i) Vehicle systems, components or separate technical units [(excluding ‘sealing applications’, batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical | There is sufficiently strong evidence that the substitution potential is low at EiF for several applications.<br><br>In addition, there are no drop-in alternatives for use in existing equipment for mobile air conditioning and heat pumps, and for transport refrigeration.<br><br>The added time offered by the 12-year derogations provides opportunities to develop and implement alternatives, reducing both impacts on manufacturers, such as producer surplus losses, and impacts on end-users if suitable alternatives are identified. This is particularly important when it comes to applications that are strictly necessary for safety or environmental performance of vehicles. | It is estimated that RO1 would reduce emissions across all transport uses by 94% (with and without EoL emissions). Emissions of PFASs to the environment would be reduced by 697 397 t over the 30 -year assessment period (2025-2055) (566 843 t without EoL emissions).<br><br>The effectiveness of RO2 is estimated to be 61% (61% without EoL emissions). Emissions of PFAS to the environment would be reduced by 446 904 t over the 30-year assessment period (2025-2055)<br>(363 601 t without EoL emissions). | | RO2 is deemed to be a restriction option that is not effective enough as it does not reach the desired minimum effectiveness level based on the approach for concluding on proportionality developed by the Dossier Submitters. RO1 is deemed to be likely not proportionate. The costs associated with RO3 (described in detail in Annex E) are deemed to be high and are thus higher than the costs associated with RO2, but lower than the costs associated with RO1. Based on the estimated effectiveness of RO3 (64% including EoL) and the estimated magnitude of costs, RO3 is deemed to be a restriction option that is also not effective enough as it does not achieve the desired |

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[50] This includes: Foam mouldings; Tubes and hoses in combustion engine systems; Protective coatings and paints for transport vehicles; Hydrophobic coatings for windshields; Cable liners & coatings for transport vehicles, including high-voltage insulators; Anti-fouling coatings for ships; Surface coatings for exterior sensors; Anti-icing coating for helicopter rotors; Trim materials for vehicle interiors; Coating of insulation materials; Coatings to reduce fuel consumption and emissions; FEP based heat shrink sleeving; Liners for aerospace hoses; and Wrap for aluminium fan cases for jet engines.

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | textiles*)] that are subject to EU vehicle type approval, where the type approval was obtained within 13.5 years after EiF (e.g. motor vehicles within the scope of Regulation (EU) 2018/858, (EU) 2019/2144 or Directive 2007/46/EC, agricultural and forestry vehicles with the scope of Regulation (EU) 167/2013, aircraft within the scope of Regulation (EU) 2018/1139 or (EU) 748/2012, watercraft within the scope of Directive 2013/53/EU or 2009/45/EC, and rail vehicles within the scope of Regulation (EU) 2016/797 or Directive (EU) 2016/798); OR<br>ii) Systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and | The 5-year derogations will provide time to substitute PFAS in uses where alternatives have been identified but are not yet ready for the mass market or where further development systems and integration with other vehicle components is still required.<br>The time-unlimited derogation will allow for the avoidance of costs related to the premature redundancy of relevant equipment.<br>Conclusion: Costs are therefore expected to decrease from very high costs under RO1 to moderate costs under RO2. | The effectiveness of the restriction option is thus reduced considerably as a result of the derogations.<br>The expected additional emissions of RO2, compared to RO1, are 203 242 t (without EoL emissions) and 250 494 t (with EoL emissions) | | minimum effectiveness level of 70%. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | electrical systems, HVACR, technical textiles*)] in vehicles that are not within the scope of paragraph a, where the use of fluoropolymers or perfluoropolyethers are strictly necessary for safety or environmental performance of those vehicles until 13.5 years after EiF. e.g. braking, restraint, lighting/signalling, driver assistance systems, emission control.<br>• Additives to hydraulic fluids in transport vehicles.<br>• Refrigerants in mobile air conditioning systems in all vehicles other than light duty electrical vehicles.<br><br>A **time-unlimited** derogation after the transition period proposed for:<br>• Maintenance and refilling of mobile air conditioning/heat | | | | |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | pump and transport refrigeration equipment placed on the market before the end of the 18-month general transitional period (or placed on the market on the basis of an applicable derogation) | | | | |
| **Electronics and semiconductor (Annex E.2.11.)** | | | | | |
| Includes:<br>• Electronics<br>• Semiconductors | **5-year** derogation after the transition period **proposed** for:<br>• Coating and films on displays and lenses of electronic complex objects<br>**12-year** derogation after the transition period **proposed** for:<br>• Heat transfer fluid for vapor phase soldering Wires and cables (incl. connectors)<br>• Insulation material of electronic components<br>• Coating and films of electronic components | • There is sufficiently strong evidence that the substitution potential is low for all uses for which a derogation has been proposed under RO2. The proposed derogations would give manufacturers and users the opportunity to develop and implement alternatives, thereby reducing producer surplus losses, employment losses (and the associated social costs) as well as the impacts on end-users. Considering that for several uses alternatives still have to be developed and that for a high share of the several sub-uses requalification and recertification procedures are in place, | The effectiveness of a ban with all use-specific derogations (**RO2**) is estimated to reduce emissions across all uses in the electronics and semiconductor sector.<br>**Estimated** additional emissions for all the proposed derogations in RO2 compared to RO1 are 14 341 t (13 089 t excluding end of life emissions).<br>The effectiveness of RO2 compared to RO1 is 79% (80%) compared to 98% (98%) | | RO1 is deemed to be likely not proportionate due to very high costs. If feasible alternatives are identified and developed during the derogation period, the costs for society will be moderate. RO2 is deemed to be a restriction option that is likely proportionate. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | (excluding displays and lenses)<br>- Printed circuit boards and antennas<br>- Photonics<br>- Anti-drip agents in plastic of electronic components<br>- Heat transfer fluids for 2-phase immersion cooling<br>- Semiconductor manufacturing | a 12-year derogation is justified to reduce cost impacts.<br>- For one use a 5-year derogation is justified as stakeholders indicated that no more than 5 years are needed for full substitution.<br>- Conclusion: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | | | |
| **Energy (Annex E.2.12.)** | | | | | |
| Sector as a whole | **5-year derogation** after the transition period **proposed** for:<br>Front- and backsheets for photovoltaic cells<br>Coatings for separators in batteries<br>PTFE nozzles in load break switches for high voltage switchgear<br>12-year derogation after the transition period **proposed** for:<br>- Fuel cells and electrolysis technology<br>- Binders and electrolytes in batteries | There is sufficiently strong evidence that the substitution potential is low for coatings for separators in batteries and PTFE nozzles in load break switches for high-voltage switchgear at EiF. The added time offered by the 5-year derogation provides opportunities to develop and implement alternatives, reducing producer surplus losses, employment losses (and the associated social costs) as well as the impacts on end-users.<br>There is sufficiently strong evidence that the substitution potential is low for backsheets and frontsheets at EiF. The added time offered by the 5- | It is estimated that RO1 would reduce emissions across all uses within the energy sector by 99% (with and without EoL emissions).<br>Emissions of PFASs to the environment would be reduced by 467 843 t with EoL over the assessment period (2025-2055) (362 097 t without EoL).<br>The effectiveness of a ban with all use-specific derogations (**RO2**) is estimated to reduce emissions across all uses in the energy sector by 89% | | RO1 is deemed to be likely not proportionate due to very high costs. If feasible alternatives are identified and developed during the derogation period, the costs for society will be low to moderate. RO2 is deemed to be a restriction option that is likely proportionate. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | year derogation provides opportunities for non-EEA manufacturers to develop and implement alternatives, thereby reducing supply shortages in the EEA as well as reducing producer surplus losses, employment losses (and the associated social costs) as well as the impacts on end-users.<br>There is sufficiently strong evidence that the substitution potential is low for fuel cells and electrolysis technology and binders and electrolytes in batteries at EiF. The added time offered by the 12-year derogation provides opportunities to develop and implement alternatives, reducing producer surplus losses, employment losses (and the associated social costs) as well as the impacts on end-users.<br>Conclusion: Costs are expected to decrease from very high costs under RO1 to low to moderate costs under RO2. | (90% without EoL emissions).<br>**RO2**: Emissions of PFASs to the environment would be reduced by **426 972 t** over the assessment period (2025-2055) (**332 738** t without EoL emissions)<br>Front- and backsheets in photovoltaic cells: The effectiveness is estimated to be 99% with and without EoL emissions. Emissions of PFASs to the environment would be reduced by 467 529 t over the assessment period (2025-2055) (362 007 t without EoL emissions).<br>Separator coatings for batteries: The effectiveness is estimated to be 98% (97% without EoL emissions). Emissions of PFASs to the environment would be reduced by 459 016 t over the assessment period | | |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | | (2025-2055) (353 437 t without EoL emissions).<br>PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers: The effectiveness is estimated to be 99%with and without EoL emissions. Emissions of PFASs to the environment would be reduced by 467 830 t over the assessment period (2025-2055) (362 089 t without EoL emissions).<br>Fuel cells and electrolysers: The effectiveness is estimated to be 99% with and without EoL emissions. Emissions of PFASs to the environment would be reduced by 466 878 t over the assessment period (2025-2055) (361 740 t without EoL emissions).<br>Binders and electrolytes in batteries: The effectiveness is | | |

| **Use** | **Derogations under RO2** | **Cost and other impacts of RO2 (in comparison to RO1)** | **Environmental impact of RO2 (in comparison to RO1)** | **Other aspects** | **Overall evaluation of proportionality** |
|---|---|---|---|---|---|
| | | | estimated to be 92% (93% without EoL emissions). Emissions of PFASs to the environment would be reduced by 437 103 t over the assessment period (2025-2055) (341 853 t without EoL emissions). | | |
| **Construction products (Annex E.2.13.)** | | | | | |
| Includes:<br>• Architectural coatings and paints<br>• Coil coating<br>• Polymer additives used for fire safety purposes<br>• Film/foil for greenhouses<br>• Processing aids for production of non-PFAS polymers/ plastics<br>• Bridge and building bearings<br>• Window frames<br>• Plumbing applications<br>• Surface protection<br>• Wetting/levelling agents, e.g. in coating, paints and adhesives | 12-year derogation after the transition period **proposed** for:<br>• Polymer additives used for fire safety purposes<br>• Bridge and building bearings | There is sufficiently strong evidence that the substitution potential is low for polymer additives used for fire safety purposes and bridge and building bearings at EiF. The added time offered by the 12-year derogation provides opportunities to develop and implement alternatives, reducing producer surplus losses, employment losses (and the associated social costs) as well as the impacts on end-users. The decrease in flame retardancy and anti-dripping properties of plastics as a result of the absence of suitable polymer additives, and the potential increase in damage to human life and property will, for example, be avoided. | The derogations cover mainly fluoropolymers and perfluoropolyethers. RO2 achieves a total PFAS emission reduction with EoL of about 780 t with EoL emissions (514 t without EoL emissions) compared to RO1. The derogation can, therefore, be expected to reduce the effectiveness of the restriction to about 95%. The emission reduction of RO2 compared with the baseline are estimated to be 230 314 t with EoL emissions (209 648 t without EoL emissions) over 30 years. | Not applicable. | RO1 is deemed to be likely not proportionate due to very high costs. If feasible alternatives are identified and developed during the derogation period, the costs for society will be moderate. RO2 is deemed to be a restriction option that is likely proportionate. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| • Processing aids for the production of construction articles<br>• Window film manufacturing<br>Fluoropolymers account for the majority of the use of PFASs in relation to construction products. |  | Conclusion: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. |  |  |  |
| **Lubricants (Annex E.2.14.)** |  |  |  |  |  |
| Sector as a whole<br>Fluoropolymers account for a high proportion of the use of PFASs in lubricants or lubricant additives | 12-year derogation after the transition period **proposed** for:<br>• Industrial and professional uses of ubricants or lubricant additives | The losses of functionality identified under RO1 are likely to be avoided, while costs related to reformulation and development will be spread out over a longer period of time. | The effectiveness of a ban (RO1) is estimated to be 96%, with and without EoL emissions. Emissions of PFASs to the environment would be reduced by 95 834 t with EoL over the assessment period (2025-2055) (93 114 t without EoL).<br>The effectiveness of RO2 is estimated to be 62%. Emissions of PFASs to the environment would be reduced by 62 102 t with EoL over the assessment period (2025-2055) (60 339 t without EoL). Additional emissions of PFASs to the environment are estimated to be 33 732 |  | • RO2 is found to be a more proportionate restriction option than RO1. Due to the associated moderate costs and very low effectiveness, RO2 is deemed to be likely proportionate. RO1 is, in contrast, deemed to be a restriction option that is likely not proportionate due to the very high costs associated with this restriction option. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | | t over the assessment period (2025-2055) (32 774 t without EoL emissions). | | |
| **Petroleum and mining (Annex E.2.15.)** | | | | | |
| Includes:<br>• Tracers<br>• Anti-foaming agents<br>•<br>No use of fluoropolymers in the above-mentioned uses. | **12-year** derogation after the transition period **proposed** for:<br>• Gas and oil tracers | Costs will decrease from HIGH to LOW, if technically and economically feasible alternatives are identified in sufficient numbers during the derogation period. If feasible alternatives are not identified, the costs are expected to be the same as without a derogation. | It is estimated that RO1 would reduce emissions by 94% compared to the baseline (from 59 t to 3.3 t over the period 2025 to 2055).<br>There is **sufficiently strong quantitative evidence** that a 12-year derogation of PFAS use in gas and oil tracers causes additional emissions being only slightly higher compared to RO1 (3.4 t compared to 3.3 t under RO1). The increase of emissions compared to RO1 is 0.2%. | | RO1 is likely not proportionate due to high expected costs.<br>• If feasible alterantives for oil and gas tracers are identified in sufficient numbers during the derogation period, RO2 is proportionate. |
| **Printing applications (Annex E.2.16.)** | | | | | |
| Includes:<br>• Toners<br>• Latex printing inks<br>• PTFE wax<br>• Pigments and colourants<br>• PTFE powders | **12-year** derogation after the transition period **proposed** for:<br>• Toners<br>• Latex printing inks Electrophotographic press units<br>• Kinetic printing components | There is sufficiently strong evidence that there is a low substitution potential for toners, latex printing inks, electrophotographic press units, kinetic printing components and photosensitive materials at EiF. The added time offered by the 12-year derogation | It is estimated that RO1 would reduce emissions by 96% compared to the baseline (from 722 t to 25.6 t over the period 2025 to 2055).<br>RO2 achieves a total PFAS emission reduction with EoL of about 580.2 t | n/a | RO2 is found to be a more proportionate restriction option than RO1. Due to the associated moderate costs and a high effectiveness (of approximately 80%), RO2 is deemed to be likely proportionate. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| • Photsensitive materials<br>• Surfactant used in printing equipment<br>• Electrophotographic press units<br>• kinetic printing components<br>• Printing plates (offset and letterpress printing)<br>• Rollers<br>Use of fluoropolymers in relation to printing applications is significant. | • Photosensitive materials<br>A **time-unlimited** derogation after the transition period proposed for:<br>• Toners for use in existing equipment put on the market until 13.5 years after EiF<br>• Latex printing inks for use in existing equipment put on the market until 13.5 years after EiF | provides opportunities to deverlop, (certify) and distribute alternative products, reducing turnover and producer surplus losses of manufacturers of printing equipment and the printing service industry, reducing job losses and impacts on other end-users of printing equipment or customers of printing service companies.<br>For toners and latex printing inks, a time-unlimited derogation for their use in existing equipment will avoid the costs on downstream users that are associated with the early redundancy of equipment.<br>Conclusion: Costs are expected to decrease from high costs under RO1 to moderate costs under RO2. | compared to the baseline (562.2 t without EoL emissions). The derogations can, therefore, be expected to reduce the effectiveness of the restriction to 80%. The extra emissions of RO2 compared with RO1 are estimated to be 116.2 t over 30 years (114.6 t without EoL emissions).<br>The time-unlimited derogation will also reduce the amount of waste compared to RO1. | | RO1 is, in contrast, deemed to be likely not proportionate due to the high costs associated with the restriction option which has an effectiveness (of around 96%). |
| **Sealing applications (Annex E.2.17.)** | | | | | |
| Use of fluoropolymers in relation to sealing applications is significant. | **12-year** derogation after the transition period **proposed** for:<br>Industrial use in sealing applications | There is sufficiently strong evidence that there is a low substitution potential for sealing applications at EiF. The added time offered by the 12-year derogation provides opportunities to deverlop, certify and distribute alternative products, reducing turnover and producer surplus losses | RO2 achieves a total PFAS emission reduction with EoL of about 19 147 t compared to the baseline (14 959 t without EoL emissions). The derogation can, therefore, be expected to reduce the effectiveness of the | n/a | The costs associated with RO2 (moderate) are substantially lower than the costs of RO1 (very high). Based on the estimated effectiveness of RO1 (96% including EoL) and RO2 (66% including EoL), and the estimated magnitude of costs, RO2 is not considered to be |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | of sealing producers, reducing job losses and impacts on other end-users of sealing applications.<br><u>Conclusion</u>: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | restriction. The effectiveness is approximately 66%. The extra emissions of RO2 compared with RO1 are estimated to be 8 758 t over 30 years (6 842 t without EoL emissions). | | sufficiently effective as it does not achieve the desired minimum effectiveness level of 70% over the assessment period while RO1 is deemed likely not proportionate, based on its very high costs |
| **Machinery applications (Annex E.2.18.)** | | | | | |
| | **12-year** derogation after the transition period **proposed** for:<br>Industrial use in machinery applications | There is sufficiently strong evidence that there is a low substitution potential for machinery applications at EiF. The added time offered by the 12-year derogation provides opportunities to develop, certify and distribute alternative products, reducing turnover and producer surplus losses of producers of machinery applications, reducing job losses and impacts on other end-users of machinery applications.<br><u>Conclusion</u>: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | RO2 achieves a total PFAS emission reduction with EoL of about 833 t compared to the baseline (675 t without EoL emissions). The derogation can, therefore, be expected to reduce the effectiveness of the restriction. The effectiveness is approximately 66%. The extra emissions of RO2 compared with RO1 are estimated to be 381 t over 30 years (309 t without EoL emissions). | | The costs associated with RO2 (moderate) are substantially lower than the costs of RO1 (very high). Based on the estimated effectiveness of RO1 (96% including EoL) and RO2 (66% including EoL), and the estimated magnitude of costs, RO2 is not considered to be sufficiently effective as it does not achieve the desired minimum effectiveness level of 70% over the assessment period while RO1 is deemed likely not proportionate, based on its very high costs. Based on the estimated effectiveness of RO3 (42% including EoL) and the estimated magnitude of costs, RO3 is deemed to be a restriction option that is also not effective |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | | | | | enough as it does not achieve the desired minimum effectiveness level of 70%. |
| **Other medical applications (Annex E.2.19)** | | | | | |
| Includes:<br>- Fluorinated gases as propellants in pMDIs<br>- SFAs as excipients in medicinal products for ophthalmic and dermatological therapies<br>- PFAS-coating in release liners and backing film in transdermal patches<br>- Fluoropolymers in blisters for solid oral dose formulations<br>- Fluoropolymer-coated rubber stoppers in vials/flasks for injectable medicinal products<br>- Fluoropolymer-coated packaging of | **5-year** derogation after the transition period **proposed** for:<br>- Fluorinated gases as propellants in pMDIs<br>- Fluoropolymers in blisters for solid oral dose formulations<br><br>**12-year** derogation after the transition period **proposed** for:<br>- SFAs as excipients in medicinal products for ophthalmic and dermatological therapies<br>- PFAS-coating in release liners and backing film in transdermal patches<br>- Fluoropolymer-coated rubber stoppers in vials/flasks for injectable | There is sufficiently strong evidence that there is a low substitution potential for then uses covered by the proposed derogations at EiF.<br><br>The 5-year derogations for fluorinated gases as propellants in pMDIs and fluoropolymers in blisters for solid oral dose formulations allow time for implementation of already identified feasible alternatives.<br><br>The 12-year derogations allow time for the identification, development and approval of feasible alternatives. If this process is succesful, the eventual socio-economic costs due to reduced functionality would be avoided.<br><br>Conclusion: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | The effectiveness of a ban with all use-specific derogations (**RO2**) is estimated to reduce emissions for other medical applications.<br><br>**Estimated** additional emissions for all the proposed derogations in RO2 compared to RO1 are 13 779 t (13 757 t excluding end of life emissions).<br><br>The effectiveness of RO2 compared to RO1 is 73% (73%) compared to 91% (91%) | The Dossier Submitters note that by 1 July 2028, the Commission shall publish a report assessing the impact of the F-gas regulation (2024/573, article 35.4) on the health sector, including on the availability of metered dose inhalers for the delivery of pharmaceutical ingredients. The Dossier Submitters recommend that the Commission includes the implications of the proposed restriction of PFASs used in metered dose inhalers in that assessment. | The costs associated with RO2 (moderate) are substantially lower than the costs of RO1 (very high). Based on the estimated effectiveness of RO1 (91% including EoL) and RO2 (74% including EoL), RO2 is deemed to be likely proportionate.<br>RO1 is, in contrast, deemed to be likely not proportionate due to the high costs associated with the restriction option. |

| **Use** | **Derogations under RO2** | **Cost and other impacts of RO2 (in comparison to RO1)** | **Environmental impact of RO2 (in comparison to RO1)** | **Other aspects** | **Overall evaluation of proportionality** |
|---|---|---|---|---|---|
| transdermal patches<br>- Fluorinated HDPE packaging<br>- Fluoropolymer-coated canisters in pMDIs<br>- Fluoropolymer-coated plungers in pre-filled syringes<br>- PFAS in pre-filled injection pens & autoinjectors<br><br>All uses except fluorinated gases as propellants in pMDIs, SFAs as excipients in medicinal products for ophthalmic and dermatological therapies and fluorinated HDPE packaging are fluoropolymer uses. | medicinal products<br>- Fluoropolymer-coated canisters in pMDIs<br>- Fluoropolymer-coated plungers in pre-filled syringes<br>- PFAS in pre-filled injection pens & autoinjectors | | | | |
| **Military applications (Annex E.2.20.)** | | | | | |
| **Sector as a whole**<br><br>Use of PFAS (fluropolymers, perfluoropolyethers, f- | **12-year** derogation after the transition period **proposed** for:<br>All uses of PFAS in military applications, | There is sufficiently strong evidence for low substitution potential at EiF and a transition time of 10 to 20 years would be required. | The effectiveness of a ban with all proposed use-specific derogations for 12 years (**RO2**) is estimated to reduce | | The costs associated with RO2 (moderate) are substantially lower than the costs of RO1 (very high). Based on the |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| gases) is expected to be significant. | overriding derogations which may include military equipment assessed under other sectors unless those derogations extend for a period longer than 12-years. | No derogation or a 5-year derogation would therefore both be insufficient for substitution and avoidance of Very High assumed costs.<br>Under a 12-year derogation some military applications are expected to be able to substitute to alternatives. Uncertainty does exist based on the transition timeline as to the proportion of all applications which may be able to substitute within the derogation. Assuming most applications can substitute within the 12-year derogation costs are expected to reduce.<br>Conclusion: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | emissions across all military applications by 72% (72% without EoL emissions).<br>**RO2**: Emissions of PFASs to the environment would be reduced by **49 860** t over the assessment period (2025-2055) (27 430 t without EoL emissions).<br>The effectiveness of a ban with a derogation for all uses in military applications (**RO2**) is estimated to reduce emissions across all uses.<br>The effectiveness of RO2 compared to RO1 is 72% (72%) compared to RO1 of 90% (90%).<br>**Estimated** additional emissions for all the proposed derogations in RO2 compared to RO1 are 17 372 t (9 557 t excluding end of life emissions). |  | estimated effectiveness of RO1 (97% including EoL) and RO2 (72% including EoL), RO2 is deemed to be likely proportionate.<br>RO1 is, in contrast, deemed to be likely not proportionate due to the high costs associated with the restriction option. |
| **Explosives (Annex E.2.21.)** |  |  |  |  |  |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| **Sector as a whole**<br>Use of fluropolymers (fluoroelastomers) | **12-year** derogation after the transition period **proposed** for:<br>- All PFAS used in explosives for military applications | For mining and blasting, transport and professional and consumer uses no differences are expected between RO1 and RO2 due to uncertain substitution potential.<br>For military applications there is sufficiently strong evidence for low substitution potential at EiF and a transition time of 10 to 25 years would be required.<br>No derogation or a 5-year derogation would therefore both be insufficient for substitution and avoidance of Very High assumed costs.<br>Under a 12-year derogation some military applications of explosives are expected to be able to substitute to alternatives. Uncertainty does exist based on the transition timeline as to the proportion of all applications which may be able to substitute within the derogation. Assuming most applications can substitute within the 12 year derogation costs are expected to reduce. | The effectiveness of a ban with all proposed use-specific derogations for 12 years (**RO2**) is estimated to reduce emissions across all military applications ofin explosives by 95% (95% without EoL emissions).<br>**RO2**: Emissions of PFASs to the environment would be reduced by 1 581 t over the assessment period (2025-2055) (1 575 t without EoL emissions).Not<br>The effectiveness of RO2 is 95% (95%) compared to RO1 of 96% (96%).<br>**Estimated** additional emissions for all the proposed derogations in RO2 compared to RO1 are 22 t (22 t excluding end of life emissions). | Not applicable. | Impacts of RO2 are equal to RO1, as the proposed derogation has minimal impacts. Data relating to costs are uncertain based on limited available information. |

| **Use** | **Derogations under RO2** | **Cost and other impacts of RO2 (in comparison to RO1)** | **Environmental impact of RO2 (in comparison to RO1)** | **Other aspects** | **Overall evaluation of proportionality** |
|---|---|---|---|---|---|
| | | Conclusion: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | | | |
| **Technical textiles (Annex E.2.22.)** | | | | | |
| Includes:<br>• Outdoor technical textiles<br>• Architectural membranes, other tensile fabrics and other construction applications<br>• Filtration and separation media<br>• Removable covers for industrial process equipment<br>• Technical textiles for medical applications<br>• Technical textiles for transport vehicles<br>Fluoropolymers account for the majority of the use of PFASs in technical textiles. | **5-year** derogation after the transition period **proposed** for:<br>• Industrial use of fluoropolymers in filtration and separation media for water treatment and purification;<br>• Sound-permeable and vent filters for electrical and electronic equipment; and<br>• Technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay.<br>**12-year** derogation after the transition period **proposed** for:<br>• HEPA (H 13-14) and ULPA (U 15-17) | The added time offered by the 5-year and 12-year derogations provides opportunities to identify (where relevant), develop and implement alternatives, reducing both producer surplus losses to directly affected companies and producer surplus losses in the wider supply chain. In addition, impacts on end-users resulting from the absence of several technical textile products are avoided. Under RO2, the absence of suitable filtration and separation media for the filtration and separation of air and other gases for many technically demanding or specialised applications is, for example, avoided. This also avoids the associated impacts for end-users which are described as ranging up to temporary business closures for downstream use | It is estimated that RO1 would reduce emissions across all uses of technical textiles by 97% (with and without EoL emissions). Emissions of PFASs to the environment would be reduced by 60 755 t over the 30-year assessment period (2025-2055) (57 957 t without EoL emissions).<br>The effectiveness of RO2 is estimated to be 84% (with and without EoL emissions). Emissions of PFASs to the environment would be reduced by 52 518 t over the 30-year assessment period (2025-2055) (50 098 without EoL emissions).<br>The expected additional emissions of RO2, | n/a | RO1 is deemed to be likely not proportionate due to very high costs. If feasible alternatives are identified and developed during the derogation period, the costs for society will be moderate. RO2 is deemed to be a restriction option that is likely proportionate. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
| | filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases, excluding general (HVAC) ventilation;<br>- Oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries;<br>- Industrial use as media in liquid-liquid separation;<br>- Woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795 (with the scope of the derogation also applying to | industries. Equally, the absence of (i) many other products used for filtration and separation purposes (including vents), (ii) reuseable medical textiles and (iii) suitable textiles for noise, vibration and harshness (NVH) insultation and ignition protection in engine bays are also avoided under RO2. In relation to technical textiles for transport vehicles, this avoids a potential reduction in technical standards in the industry and the risk for higher loss of life in case of accidents.<br><br>Medium welfare losses or additional costs as a result of lower functionality are nevertheless expected, e.g.:<br>- Negative impacts on the service life duration of outdoor technical textiles and associated costs for, e.g. repairing seams, as well as similar impacts in relation to e.g. permanent load-bearing architectural elements; and | compared to RO1, are 8 237 t (with EoL emissions) and 7 865 t (without EoL emissions). | | |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
|  | impregnation agents, and associated processes, used for re-impregnating technical textiles for medical applications); and<br>- Technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection. | - Some negative impacts on e.g. filtration performance, service life duration and the energy efficiency of filtration processes relating to water treatment and purification.<br>In addition, some consumer surplus losses as a result of price changes triggered by the substitution costs incurred by companies are expected.<br>Employment losses are expected to be significantly reduced under RO2 but not avoided completely. Medium employment losses are expected under RO2 given that some producers of permanent load-bearing elements are expected to close business (e.g. as a result of the shrinking of the market for architectural membranes) and that producers of removable covers for industrial process equipment are expected to close business given that relevant products are |  |  |  |

| **Use** | **Derogations under RO2** | **Cost and other impacts of RO2 (in comparison to RO1)** | **Environmental impact of RO2 (in comparison to RO1)** | **Other aspects** | **Overall evaluation of proportionality** |
|---|---|---|---|---|---|
| | | expected to be replaced by non-textile products.<br>Conclusion: Costs are expected to decrease from very high costs under RO1 to moderate costs under RO2. | | | |
| **Broader industrial uses (Annex E.2.23.)** | | | | | |
| Includes:<br>Hydraulic fluids<br>Solvents and precision cleaning<br>Catalyst and processing aids | **5-year** derogation after the transition period **proposed** for:<br>ionic liquids in industrial uses<br>**12-year** derogation after the transition period **proposed** for:<br>Solvents in industrial uses<br>**12-year** derogation after the transition period **proposed** for:<br>catalysts and processing aids in industrial uses. | Assuming that suitable alternatives will be identified for the uses for which alternatives do not exist at EiF, the costs are expected to be:<br>**Impacts on users**<br>The economic impacts would arise due to identification of alternatives and costs are expected to be lower than for RO1.<br>**Impacts on industrial downstream users**<br>No information on this impact has been identified.<br>**Welfare losses or additional costs as a result of non-availability of articles**<br>For some uses, alternative production methods have been described. It can be assumed that no welfare | It is estimated that RO1 would reduce emissions across all uses of broader industrial uses by 96% (with and without EoL emissions). Emissions of PFASs to the environment would be reduced by 9 228 t over the 30-year assessment period (2025-2055) (9 027 t without EoL emissions).<br>The effectiveness of RO2 is estimated to be 68% with EoL emissions (68% without EoL emissions). Emissions of PFASs to the environment would be reduced by 6 556 t over the 30-year assessment period | | RO1 is deemed to be likely not proportionate due to high costs. If feasible alternatives are identified and developed during the derogation period, the costs for society will be moderate. RO2 is not considered to be sufficiently effective as it does not achieve the desired minimum effectiveness level of 70% over the assessment period. Despite this, RO2 is deemed to be a more proportionate restriction option than RO1. The associated moderate costs and very low effectiveness make RO2 to be deemed likely proportionate. |

| Use | Derogations under RO2 | Cost and other impacts of RO2 (in comparison to RO1) | Environmental impact of RO2 (in comparison to RO1) | Other aspects | Overall evaluation of proportionality |
|---|---|---|---|---|---|
|  |  | losses will occur.<br>Overall, the costs associated with all relevant applications are deemed to be moderate which is lower than for RO1. | (2025-2055) (6 374 t without EoL emissions).<br>The expected additional emissions of RO2, compared to RO1, are 2 672 t with EoL emissions (2 653 t without EoL emissions). |  |  |

Table 16 summarises the outcomes of the assessment of costs and benefits for the manufacturing of PFAS. The Dossier Submitters note that the format of this table differs from the assessments for other sectors and that no matrix to assess the proportionality of the ROs was prepared because alternatives have not been assessed and because environmental impacts as well as cost impacts are partially dependent on regulatory measures for all other assessed sectors.

**Table 16. PFAS manufacturing – Summary table on assessment of costs and benefits.**

| Restriction option | Duration of derogation | Environmental impact | Cost impact | Proportionality |
|---|---|---|---|---|
| **RO1; Full restriction of all production of PFAS** | n.a. | The effectiveness of a ban is estimated to be 97% (97% without EoL emissions).<br>Emissions of PFAS to the environment would be reduced by 48 795 t over the assessment period (2025-2055) including EoL emissions; 48 783 t without EoL emissions. | **High producer surplus losses (order of magnitude: ~€42 billion NPV over 30 years)** as a result of business closures [sufficiently strong evidence] due to (i) a high share of business closures [sufficiently strong evidence], (ii) high producer surplus losses at company level due to high margins [sufficiently strong evidence], (iii) an unknown offsetting potential, i.e. producer surplus losses are balanced out to some extent by producer surplus gains by producers of alternative-based products [no evidence] and (iv) high producer surplus losses in the wider supply | High costs and high effectiveness. The restriction option is therefore considered as likely not proportionate.<br>This conclusion does not consider impacts on downstream users resulting from unavailability of EEA-manufactured PFAS. |

| | | | | |
|---|---|---|---|---|
| | | | chain.<br>**High employment losses (order of magnitude: ~€1.5 billion NPV)** as a result of high share of business closures. | |
| **RO2; Restriction of all production of PFAS except for derogated uses** | Up to 12 years depending on derogations for downstream uses of PFAS | The effectiveness of a ban with a 12 year derogation is estimated to be between 70% and 100% depending on the behavioral reaction of manufacturers (same effectiveness without EoL emissions).<br>Emissions of PFAS to the environment would be reduced by 35 376 to 50 532 t over the assessment period (2025-2055) including EoL emissions; 35 368 to 50 250 t without EoL emissions. | **No information** is available to quantify a difference in the producer surplus losses and employment losses between RO1 and RO2.<br>**Weak evidence** available that producer surplus losses and employment losses from business closures are reduced compared to RO1 | High costs and high effectiveness based on the conclusion that the majority of business would close. The restriction option is therefore considered as likely not proportionate.<br>This conclusion does not consider impacts on downstream users resulting from unavailability of EEA-manufactured PFAS. |
| **RO3a; Derogation for the** production of PFAS with or without the use of fluorinated polymerisation aids in the production of polymeric PFAS under controlled conditions with average emission factors (= Annual emission of PFAS / total annual amount of PFAS manufactured on site) not exceeding a) 0.0090% to air, 0.0010% to water and 0% to soil for emissions of non-polymeric PFAS | Up to 12 years depending on derogations for downstream uses of PFAS | The effectiveness of a ban with a 12 year derogation is estimated to be between 91% and 100% depending on the behavioral reaction of manufacturers (same effectiveness without EoL emissions).<br>Emissions of PFAS to the environment would be reduced by 46 204 to 50 532 t over the assessment period (2025-2055) including EoL emissions; 46 196 to 50 250 t without EoL emissions. | Producer surplus losses and employment losses from business closures are reduced compared to RO1 and RO2 due to an unknown share being able to continue manufacturing. No evidence available to conclude regarding the question whether manufacturers would be able to offset additional costs for emission control measures over a period of 13.5 years after Eif.<br>**High producer surplus losses and high employment** losses are expected at latest after 13.5 years when all or most business is expected to close based on the fact that most demand previously resulting from derogated PFAS uses ceases to exist | High effectiveness. High costs based on the conclusion that the majority of business closes at some point. The restriction option is therefore considered as likely not proportionate.<br>This conclusion does not consider impacts on downstream users resulting from unavailability of EEA-manufactured PFAS. |

| | | | | |
|---|---|---|---|---|
| residues from polymerization aid technology in fluoropolymer manufacturing until 2030;<br>b) 0.0030% to air, 0.0006% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing from 2030 onwards;<br>c) 0.01% to all compartments for all PFAS emissions not mentioned above from sites manufacturing polymeric and non-polymeric PFAS from 2030 onwards. | | | and the derogation for export of PFAS ends. | |
| **RO3b; Derogation for the** production of PFAS with or without the use of fluorinated polymerisation aids in the production of polymeric PFAS under controlled conditions with average emission factors (= Annual emission of PFAS / total annual amount of PFAS manufactured | No time limit | The effectiveness of a ban with a time-unlimited derogation is estimated to be between 90% and 93% depending on the total volume of derogated uses and export for which to produce (same effectiveness without EoL emissions).<br>Emissions of PFAS to the environment would be reduced by 45 324 to 47 060 t over the assessment period (2025-2055) including EoL emissions; 45 324 to 47 054 t without EoL emissions. | Producer surplus losses and employment losses from business closures are reduced compared to RO1, RO2 and RO3a due to an unknown share being able to continue manufacturing for a limited number of derogations and exemptions as well as for export, enabling manufacturers to offset additional costs for emission control measures over a longer period. | High effectiveness.<br>Moderate costs based on the assumption that demand will decrease over time, but that an unknown significant share of manufacturers have sufficient time to adjust manufacturing capacities accordingly thereby limiting the number of business closures. |

| | | | | |
|---|---|---|---|---|
| on site) not exceeding<br>a) 0.0090% to air, 0.0010% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing until 2030;<br>b) 0.0030% to air, 0.0006% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing from 2030 onwards;<br>c) 0.01% to all compartments for all PFAS emissions not mentioned above from sites manufacturing polymeric and non-polymeric PFAS from 2030 onwards. | | | | This conclusion does not consider impacts on downstream users resulting from unavailability of EEA-manufactured PFAS. |

## 2.5. Practicability and monitorability

The current restriction proposal covers the whole class of PFASs, amounting to more than 10 000 different compounds. Different types of PFASs are used in different products and applications according to their properties. Addressing the whole class of PFASs in all relevant applications is complex and requires a broad approach for compliance monitoring and analysis. All restriction options, i.e. RO1, RO2 and RO3 apply to products and applications unless otherwise specified.

### 2.5.1. **Practicability of restriction options**

The Dossier Submitters assessed the appropriateness of various restriction options, including a restriction option that comprised a full ban on PFASs (RO1), a ban on PFASs with use-specific transitional periods (RO2s) as well as 'additional restriction options' for certain uses that comprised other measures to address the identified risk (RO3s). Additional restriction options (RO3s) were developed based on the comments received in the consultation on the Annex XV report and their assessment is reported within the sector assessments in Annex E.

Implementability is about the compliance at entry into force, using the technology, techniques and alternatives that are available and economically feasible. RO1, a full ban on PFAS in their applications, is likely not implementable as a whole, as several specific applications have been identified for which alternatives are not expected to be available even with an 18-month transitional period. To mitigate this, RO2 was developed, ban with use-specific derogations for applications where technology, techniques and alternatives cannot be expected to be available until the end of the proposed derogations. The use-specific, time-limited derogations included in RO2 give the affected stakeholders the opportunity to implement suitable alternatives, and therefore, RO2 is considered implementable. Likewise, RO3 reflects an approach to allow the continued use of PFASs under strict conditions to minimise risks in specific applications where suitable alternatives are not yet ready in order to make RO3 as a whole implementable. Further details on the implementability of each of the RO3s is reported within the sector assessments in Annex E. Alternatives to PFASs are already being used or research and development is in a late stage, leading to the possibility for implementation in the short term for many applications. Stakeholders in several sectors are currently moving away from the use of PFASs for various reasons, e.g. customer and investor requests, legislative and regulatory actions. This indicates in a number of cases that suitable alternatives for PFASs are sufficiently available, and/or PFAS-containing products are no longer requested.

Only for uses for which stakeholders supplied sufficiently strong information demonstrating that suitable alternatives are not available, derogations are proposed. This approach was taken since derogations inevitably lead to a longer period that PFASs are being manufactured and brought to market, increasing the technical stock. Consequently, this leads to prolonged emissions of PFASs from the manufacture, use and waste phase to the environment, increasing the environmental stock which affects human health and the environment on an intergenerational level (due to the extreme persistence of the substances). Because of the concerns outlined in this proposed restriction, no derogations were proposed for uses and sectors for which no, inconclusive or weak evidence for the current absence of alternatives was submitted. A full ban of PFASs after a transition period of 18 months was considered practicable for these uses and sectors.

For a restriction to be enforceable, the authorities should be able to check the compliance of relevant actors with the restriction or other considered RMOs. All of the restriction options assessed by the Dossier Submitters (i.e., RO1, RO2 and RO3) are considered to be sufficiently enforceable. Competent authorities of EU Member States responsible for REACH enforcement activities have experience with REACH restrictions, including restrictions dealing with specific (groups of) PFASs (see section 2.2.1) in substances, mixtures and articles. Based on experiences with the existing PFAS restrictions, efficient supervision mechanisms can be set up. By combining enforcement according to several PFAS restrictions at the same time, the resources needed for enforcement are minimized and will be proportional to the avoided risk.

The enforceability of the proposed restriction is partly dependent on the availability of sufficiently efficient and effective analytical methods for enforcement and monitoring of the proposed concentration limits. The rationale for the proposed concentration limits, as well as the availability of appropriate analytical measurement methods, are discussed in section 2.5.2 below.

Enforceability by Member States, in particular for RO2, will also be facilitated by the information provided through the proposed **reporting requirements** for manufacturers, importers and formulators of PFAS-containing products that are covered by either a 13.5 year time-limited or an indefinite derogation (paragraph 7 in the proposed Annex XVII entry) derogation, see Annex E.4.1.4.

Furthermore, the proposed requirements for the development of **site-specific management plans** for manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers (paragraph 8 in proposed Annex XVII entry) will provide information that can be checked during enforcement, see Annex E.4.1.5.

Information on PFASs and type and amount of products containing PFASs can help in targeting uses and sectors for specific enforcement activities and actions. Similarly, enforcement could target manufacturers or downstream users (i.e., formulators) of fluoropolymers and perfluoropolyethers for derogated uses based on the information provided in reporting to ensure that they have an appropriate site-specific plan that details conditions of use and safe disposal.

The broad chemical scope of the proposed restriction is beneficial to enforcement, since all PFASs are covered by the scope of the restriction, with the exception of a few substances with potential for full degradation under environmental conditions. This is beneficial in avoiding discussions on applicability of the restriction and legal uncertainties when PFASs are being found during enforcement activities. For RO3s, the assessment of enforceability is reported within the sector assessments in Annex E.

It is noted that trace impurities in a chemical are usually of the same type of substance as the main component. This is because impurities are formed by additional chemical processes with the same reagents during manufacture or when reactions are incomplete. It follows that PFAS-impurities are found primarily in other PFAS-substances (e.g. PFOA in other PFAS, like FTOHs). It is therefore anticipated that it is easier to avoid PFAS impurities when working with non-PFAS chemistry, than to avoid PFOA when using other PFAS during manufacture.

Trace impurities in raw materials can be controlled by doing quality controls of the raw materials used in manufacturing processes and setting limits for PFAS impurities. This also applies to process water used in manufacturing. Unintentional contamination of products (e.g., mixtures) may also in principle arise from the use of PFAS-containing parts in manufacturing equipment (e.g. fluoropolymers in sealing or machinery applications). However, the presence of PFAS-containing parts in manufacturing equipment, even if such a use is proposed to be derogated from the conditions of the restriction, is not intended to allow any relaxation in applicable concentration limits for products i.e. contamination of manufactured products should be avoided.

From an industry perspective, it may seem complex and difficult to verify compliance with the conditions of the restriction by chemical analysis. However, good chemicals management at company level implies that information on the chemicals which have been used in the manufacture and may be found in a product should already be known. It is assumed that there is efficient information flow on the chemicals in the supply chain, and if so, companies should be able to determine whether PFASs are found in their products or not. Indeed, according to Article 34 of REACH, there is a duty to communicate new information on hazardous properties of substances up the supply chain.

Hence, industry's primary concern should be to establish efficient and effective systems to avoid the use of PFASs, or raw materials containing PFASs, when manufacturing products (unless specific uses are derogated from the proposed restriction). On the other hand, authorities should have the capability to check for compliance/non-compliance for different products by using suitable analytical method for measuring PFAS concentrations in comparison with the proposed concentration limit values.

The means of implementation of a restriction should be clear to the actors involved and the enforcement authorities in order to make it manageable, and access to the relevant information should be easy. To achieve this, the restriction is drafted similarly to existing restrictions on PFAS (e.g. PFHxA and PFAS in fire-fighting foam). Three different concentration limits for PFAS apply, and the Annex XV report explains how compliance can be checked according to these limit values. The different provisions of the restriction, including the proposed derogations, are explained in an explanatory note, and further information can be compiled in a guidance document at a later stage as necessary. The administrative burden with the restriction for the actors concerned are considered to be proportional to the risk avoided when considering the implementable options (RO2 and RO3).Although the proposed restriction may have a broad scope, it is considered to be managable. As this restriction proposal targets manufacture and placing on the market in addition to the use of PFASs, downstream users of PFASs that are typically less knowledgeable  that the products they are using contain PFASs, have knowledgeable upstream partners (manufacturers and importers). When the restriction comes into force, manufacturers and importers can no longer provide the less knowledgeable downstream users with PFASs as such or with PFAS-containing products. Therefore, awareness of the restriction conditions among downstream users will increase and possible non-PFAS alternatives for their products/applications are identified and put on the market.

The reporting requirement is mainly applicable for larger, generally more knowledgeable stakeholders (manufacturers and formulators) and requires only annual reporting of limited information for uses subject to 13.5 year time-limited derogations as well as for uses subject to indefinite derogations, making the administrative burden for both stakeholders and authorities manageable. The same applies for the site-specific management plan for fluoropolymers and perfluoropolyethers (paragraph 8 in proposed Annex XVII entry).

In conclusion, taking the above evaluation into account, all restriction options, RO1, RO2 and RO3, are considered sufficiently enforceable. RO1 is likely not implementable, and therefore also not manageable, while RO2 and RO3 are evaluated as implementable and manageable by the Dossier Submitters. Hence, RO2 and RO3 are concluded to be practical with regards to implementability, enforceability and manageability.

### 2.5.2. **Concentration limits**

#### Selected concentration limits

Demonstrating compliance with the proposed restriction when placing substances, mixtures or articles on the market is based on adherence to the following concentration limits:

1) 25 ppb for any PFAS (except polymeric PFASs),

2) 250 ppb for the sum of PFASs, optionally with prior degradation of precursors, and

3) 50 ppm for total PFASs, including polymeric PFASs*.

*) The term polymeric PFASs is defined in Figure 1 in section 1.1.1.

Compliance with the limit value **1) 25 ppb for any PFAS** (except polymeric PFASs) shall be demonstrated with information on the concentrations of specific PFASs measured by targeted

PFAS analysis, which currently comprises about 40 – 60 different PFASs (the number of PFASs that can be detected and quantified is limited by the availability of reference standards and is likely to increase over time).

Compliance with the limit value **2) 250 ppb for the sum of PFASs, optionally with prior degradation of precursors**, shall be demonstrated with information on the sum of specific PFASs measured with targeted PFAS analysis (as per concentration limit 1) or the sum of PFASs measured after a preceding degradation step, such as in the TOP assay (Total Oxidizable Precursor Assay) or other similar transformative methods. This limit is intended to address the scenario when several PFASs are present (but without any individual specific PFAS exceeding the limit value of 25 ppb). Again, the targeted PFAS analysis is not intended to include polymeric PFAS (as the methods are unsuitable and reference standards are not available). However, low-molecular weight PFAS may be formed during a transformative step (e.g. oxidative cleavage of side-chains from side-chain fluorinated polymers), and these substances should be included in the analysis and compared with the 250 ppb limit value. This is considered to be reasonable as similar processes may take place in the environment, and side-chains, once cleaved off and released, will contribute to the environmental stock.

Compliance with the limit value **3) 50 ppm for PFASs, including polymeric PFASs** shall be demonstrated with the information disclosed when the information requirement below is triggered when the concentration limit value is exceeded based on a 'total fluorine method'. Alternatively, additional analytical methods can confirm the presence of $CF_2$ and $CF_3$ units in the chemical structure of substances, see below. The concentration limit was pragmatically selected based on the existing sensitivity of the total fluorine methods For additional information on the suitability of analytical methods for the different product types relative to the concentration limits, see Appendix E.4.2.

**Information requirement:** If, as a part of an authority enforcement campaign, total fluorine exceeds **50 mg F/kg**, the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content originating of either PFASs or non-PFASs. This proposed restriction shall apply, unless the manufacturer, importer or downstream user can demonstrate that the product contains fluorine originated from substances other than those within the scope of the restriction. This could be done, for example, based on measurement data or on information obtained from the supply chain.

Currently, there are analytical methods under development that can act as alternatives to the information requirement proposed above. Methods like pyrolysis GC/MS and $^{19}$F NMR can confirm the presence of $CF_2$ and $CF_3$ units in the chemical structure of substances, and therefore, also confirm the PFAS nature of the substances, see section 2.5.5. However, the methods are still under development and currently the LOQ for pyrolysis GC/MS tends to be higher than the LOQ for CIC, which means that more development is needed until all of the fluorine content detected with CIC can be confirmed as $CF_2$ or $CF_3$. In addition, it is so far unclear whether the method can separate out substances with $CF_2$ or $CF_3$ units linked to H, Cl, Br or I, which may be out of scope.

If compliance with the 50 ppm limit cannot be adequately demonstrated, the susbstance, mixture or article should be withdrawn from the market (unless derogated), either permanently or until the total fluorine content has been reduced within the limit.

The relationship between mg F/kg sample material and mg PFASs/kg depends on the percentage of F in the molecular structure of PFASs in the sample. How to calculate this transformation is explained in Annex E.4. Like in the case of e.g. PFOS, 50 mg F/kg corresponds to 77.4 mg PFOS/kg (PFOS consists of 64.6% F). In the case that the PFAS measured is unknown, a range using the interval 50 – 80% F in the PFAS substance is suggested when converting to mg PFAS/kg sample.

All three of the concentration limits apply, unless derogated. In short, any substance, mixture or article should not contain PFAS above any of the three concentration limits unless the product is covered by an applicable derogation. Hence, a product could be checked for compliance with any of the three concentration limits, and if one limit is exceeded, the product is not in compliance with the regulation.

**Rationale for selected concentration limits**

A comprehensive overview of available analytical methods for PFAS in the different applications/sectors is found in Appendix E.4.1 to the background document. An assessment of the suitability of the methods for each of the sectors/applications relative to the proposed concentration limits is found in Appendix E.4.2.

PFASs are regarded as non-threshold substances for the purposes of risk characterization, and in order to minimize the risk, emissions should be minimized as much as possible. As a general rule concentration limits are established to prevent any intentional, i.e. technically meaningful uses of PFASs . Equally, as emissions of PFASs from all uses contribute to the overall environmental concentrations it is preferable to set concentration limits as close to zero as (technically) possible to prevent any further increase of the environmental concentrations. PFASs are fully synthetic substances with typical chemical characteristics (high number of fluorine atoms) and are not present without either intentional use or as impurities, both of which scenarios can usually be controlled. Their presence in concentrations above the concentration limits should thus be possible to avoid in products.

A zero concentration limit for PFASs is considered impractical as there are analytical challenges when measuring concentrations close to the quantification limit of a method. Hence, concentration limits are proposed as a pragmatic compromise between values associated with intentional uses and values that are still being quantifiable with chemical analysis. There are examples of previously restricted PFASs, also regarded as non-threshold substances, for which concentration limits are based on similar considerations. In Table 17 concentration limits for currently regulated PFASs are summarized.

**Table 17 Concentration limits for currently regulated PFASs**

| Substance (group) | Concentration limit(s) |
|---|---|
| PFOS<br>POPs | 10 ppm in substances or in mixtures<br>0.1% in semi-finished products or articles<br>1 µg/m$^2$ for textiles or other coated materials |
| PFHxS<br>POPs | 25 ppb for the sum of PFHxS and its salts<br>1 000 ppb for the sum of PFHxS related substances |
| C9-C14 PFCA<br>REACH | 25 ppb for the sum of C9-C14 PFCAs and their salts<br>260 ppb for the sum of C9-C14 PFCA-related substances |
| PFOA<br>POPs | 25 ppb in substances, mixtures or articles<br>1 000 ppb for sum of PFOA-related compounds |
| *PFHxA*<br>*REACH* | *25 ppb for the sum of PFHxA and its salts*<br>*1 000 ppb for the sum of PFHxA-related substances* |
| *PFAS in fire-fighting foam*<br>*REACH* | *1 mg/L (ppm) for sum of PFAS* |

1) 25 ppb for any PFAS

Drawing from previous experience with PFAS-regulations and concentration limits, **25 ppb** was selected as a starting point for a concentration limit for specific PFASs as measured with targeted PFAS analysis.

The availability of analytical methods for PFASs for different matrices, as well as their performance, is summarized in Appendix E.4.1. A comparison of the indicated **25 ppb** concentration limit with the methods used for various matrices and articles, points towards this being an appropriate concentration limit value. There are many examples of quantifications performed at and around this concentration level. It is noted that measurements at this level have not been demonstrated for all relevant matrices yet. However, it is the Dossier Submitters' understanding that it is not a prerequisite that analytical methods are fully available for the demonstration of compliance with the proposed concentration limits when submitting a restriction proposal. Consequently, the indicated **25 ppb** limit value was maintained after comparison with measurements reported and summarized in Appendix E.4.1. Besides, there is a rapid development within the field of analytical methods for PFAS and new or improved methods are regularly disclosed. The number of available analytical reference standards is currently about 40 – 60, but this number is growing as new standards are developed and put on the market.

2) 250 ppb for the sum of PFASs

The **250 ppb** concentration limit for the sum of PFASs is intended to address the scenario when several PFASs are present and without any single PFAS exceeding the limit value of 25 ppb. The intention is that PFASs measured with targeted analysis are summarized and the sum compared with the **250 ppb** concentration limit. There is a limited number of PFASs that can be measured with targeted analysis (due to limited availability of reference standards). However, transformative methods, such as the TOP assay, can disclose additional PFASs. In this assay precursors (without available reference standards) can be converted to arrowhead substances (with available reference standards) before quantification. For example, targeted PFAS analysis will not include polymeric PFAS as the methods are unsuitable and reference standards are not available, however, low-molecular weight PFAS may be formed during a transformative step (e.g. oxidative cleavage of side-chains from side-chain fluorinated polymers), and these substances should be included in the analysis and compared with the 250 ppb limit value. As all precursors in a sample also are PFASs and contribute to the overall exposure and combined effects, it is considered justified to include also concentrations as measured with TOP assay in the **250 ppb** concentration limit. After all, this represents a value closer to the true PFAS content in a sample. It is underlined that the TOP-assay measurements are only related to the sum PFAS concentration limit (250 ppb), and not to the single PFAS limit (25 ppb) as each measured transformation product may arise from several different precursors.

Different approaches to the sum PFAS concentration may be applied, with or without a preceding degradation step, and this may result in different conclusions about the PFAS content. However, either all PFASs present are quantified, or only a fraction of it is measured (as parts may be non-quantifiable and/or non-transformative under the conditions used). Different transformation methods may produce different degradation products, depending on the chemical treatment (e.g. oxidative or hydrolytic). Hence, the risk is that PFAS concentrations are underestimated rather than overestimated, i.e. the error margin is on the side of the manufacturer. Again, industry should ensure that PFASs are not used in products and processes (unless derogated), while the authorities may use any reliable (e.g. standardized or validated) method to check for non-compliance. It would not be appropriate to specify specific analytical methods for enforcement at this stage as the rapid progress in development of new and improved methods is expected to provide preferred alternatives in the future.

3) 50 ppm for total PFAS

The 50 ppm concentration limit that is to be measured with total fluorine methods, and includes polymeric PFASs, is pragmatically selected to match the sensitivity of the total fluorine methods which are to be used in the measurement and monitoring of PFASs including polymeric PFASs under this restriction. The limit value could feasibly have been proposed at a lower concentration to avoid further releases of PFASs, but the analytical methods available have their limitations with regards to the level of quantification for the various matrices. Hence, 50 ppm is in this case considered appropriate . Information about the availability and performance of total fluorine methods is available in Appendix E.4.1 and Appendix E.4.2. The proposed limit value (50 ppm) is higher than the corresponding limit value included in the PFAS in fire-fighting foam restriction (1 ppm) which is also covering total PFAS suggested measured with total fluorine methods. This is due to the fact that particularly low detection limits have been reached for this specific matrix with relevant methods.

It is to be noted that there are different variations of total fluorine methods available, including direct measurements and measurements after an extraction step, see Annex E.4.1.. Different advantages and disadvantages apply to the different variations, as described. However, either the selected method includes all organic fluorine in the measurement, or parts of it are lost in the sample preparation, like for example in an extraction step where non-extractable material can be lost (e.g. fluoropolymer material). The risk is that not all organic fluorine in a sample is detected. It should be up to the enforcement authorities to select the most appropriate total fluorine method for a specific product, and the risk of erroneous concentration determination is on their side rather than for concentrations to be measured too high.

Information requirement, total fluorine exceeds 50 mg F/kg

If total fluorine measured for a sample during enforcement exceeds 50 mg F/kg, the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content originating of either PFASs or non-PFASs. This information requirement has been introduced to solve the problem that total fluorine measurements do not differentiate between PFASs and non-PFAS fluorine-containing substances. Information from the supply chain on the chemical identity of the organic fluorine present in a sample can be used to make this differentiation. The same issue was suggested in the restriction proposal for PFAS in fire-fighting foam and solved through a similar information requirement to be put on the label of the container with foam if the foam contains organic fluorine substances above 1 mg/L but where the concentration of total PFASs is not greater than 1 mg/L (paragraph 7 of the proposed entry text). In the present restriction proposal, it is not expected that this information is put on a label for all the different products. Rather, it is suggested that such information is to be disclosed to the enforcement authorities as indicated. Whilst the information provision to enforcement authorities is described here as 'on request' the expectation is that manufacturers, suppliers and downstream users will have adequately characterised their products prior to placing them on the market and that they would be in a position to answer such an enquiry without undue delay i.e., without having to undertake additional analytical testing themselves to answer the request from enforcement authorities.

Similar obligations are put on manufacturers, importers and industrial downstream users in the microplastics restriction (entry 78 in REACH Annex XVII). Paragraph 14 states that specific information on the identity of polymers covered by the restriction is to be provided to authorities upon request, while paragraph 15 says that when polymers claimed to be out of scope of the restriction are used, technical proof for this shall be provided, without delay, to competent authorities upon their request.

As a PFAS always contains less than 100% fluorine by mass (as it also contains at least carbon), 50 mg F/kg sample will correspond to a larger concentration of PFASs.

Information from the supplier of either PFAS or non-PFAS content could be in the form of information from the supply chain regarding which PFAS are used during manufacture and that is found in the end product. Alternatively, analytical measurements identifying and quantifying the different substances that are the reason for the fluorine detected in the total fluorine measurements could be disclosed. Currently, there are analytical methods under development that can help verifying that a measured fluorine content (e.g. by TF) is PFAS or not. Methods like pyrolysis GC/MS and $^{19}$F NMR can confirm the presence of $CF_2$ and $CF_3$ units in the chemical structure of substances, and thereby confirm the PFAS nature of the substances, see section 2.5.5. However, the methods are still under development and currently the LOQ for pyrolysis GC/MS tends to be higher than the LOQ for CIC, which means that more development is needed until all of the fluorine content detected with CIC can be confirmed as $CF_2$ or $CF_3$. In addition, it is so far unclear whether the method can separate out substances with $CF_2$ or $CF_3$ units linked to H, Cl, Br or I, which may be out of scope.

Related substances

The current restriction proposal covers all PFASs as a class and as defined by a chemical structure definition in the draft entry text. This is different from the previous specific PFAS restrictions that usually apply for one specific PFAS ‘arrowhead’ and its related substances (e.g. PFOA and related substances), wherein 'related substances' are defined as substances that may degrade to the specific substance in the environment. In the present case, any precursor would also be defined as a PFAS in itself. Hence, from a concentration limit perspective, a differentiation between PFASs and their precursors, as has been done in many of the specific PFAS restrictions, is not relevant. The concentration limits will apply to any PFAS in itself, whether it is an arrowhead substance or a related substance.

Detailed examination of analytical methods

In Appendix E.4.2 the different analytical methods for PFASs have been examined in more detail for each matrix/product type, specifically with regards to their performance relative to the proposed concentration limits in this restriction proposal.

### 2.5.3. **Summary of analytical methods**

An assessment of the availability of analytical methods for PFASs is presented in Appendix E4.1. This appendix contains an Excel sheet with a collection of information on the available analytical methods for PFASs for the different products/matrices covered by the present restriction proposal. The overview includes a range of technically relevant information, including LODs and LOQs for various methods.

Targeted PFAS analysis is used to quantify individual specific PFAS, for example for the comparison with a concentration limit value for PFAS in a product. To quantify a specific PFAS reliably (e.g. for enforcement), an analytical reference standard for the specific PFAS must be available. Laboratories can currently quantify around 40 – 60 different PFASs, and this number is increasing as more reference standards become available. In addition to targeted analysis methods, the total oxidizable precursor (TOP) assay has been used by several laboratories in recent years to analyse a broader spectrum of PFASs. This method simulates accelerated environmental degradation by treating the sample with strong oxidizing agents which leads to quick oxidative degradation. The resulting degradation products are measured with the usual targeted PFAS analysis (i.e. ca. 40 – 60 PFASs) and demonstrates the presence of precursors to the PFCAs and other relevant substances. However, other methods for the quantification of precursors besides the TOP assay exist and may also be used for this purpose.

'Total fluorine' methods measure the overall amount of (organic) fluorine in a sample: total fluorine (TF), extractable organic fluorine (EOF) and adsorbable organic fluorine (AOF). The most direct approach is to measure the fluorine content in an untreated sample (i.e. direct combustion of a product sample), TF. In such an analysis all fluorine in the sample will be measured, both inorganic and organic fluorine. However, in common products inorganic fluorine is usually not present and the total fluorine can often be assumed to be organic fluorine. In any case, inorganic fluorine can be quantified by F-selective electrodes or IC without preceding combustion and subtracted from the TF value, see Annex E.4.1.4.6. On the other hand, different kinds of sample preparation may separate the different types of fluorine prior to measurement. For example, by introducing an extraction or adsorption step, EOF or AOF is measured, respectively. The total fluorine methods do not identify/differentiate between the origin of fluorine-containing organic substances, like being PFASs or non-PFASs. Therefore, the total fluorine methods will detect and quantify both PFASs and non-PFASs organic fluorine substances if present in the same sample (i.e. substances that are both in- and outside of scope of the restriction). An advantage of total fluorine methods though, compared to targeted PFAS analysis or TOP, is that they detect and quantify PFASs for which no reference standards exist, including polymeric PFASs. An additional advantage of total fluorine methods is that they are significantly faster and cheaper than targeted analyses. Hence, the use of total fluorine methods to quantify PFASs, e.g. for compliance and enforcement purposes, is practical as they are more compatible with the scope of the restriction proposal (which encompasses all PFASs). There are currently no standard methods for total fluorine. However, in Annex E.4.1.4.3 it is pointed out that in the absence of accredited or standard methods also validated methods may be applied. Total fluorine measurements have been reported for various different matrices, see Appendix E.4.1. It is also to be noted that US EPA, according to their webpages, are currently developing standard methods for Total Organic Fluorine (TOF) and Total Oxidizable Precursors (TOP assay) and the methods are said to be "coming soon", see Annex E.4.1.4.7.

Polymeric PFASs (defined in Figure 1, section 1.1.1) cannot be quantified as the specific polymers (e.g. as x mg PTFE/kg sample) in the way non-polymeric PFASs can, as reference standards are missing and the available methods are unsuitable. However, the fluorine content of polymeric PFASs will be included in the total fluorine (TF) methods unless they are left out or lost in the sample preparation.

One approach to the enforcement of a restriction of PFASs as a class is a tiered approach where targeted PFAS analyses are combined with total fluorine and non-target approaches. The sum of targeted PFAS accounts for varying fractions of the total fluorine in the sample, from very small to large, depending on the characteristics of the sample. Therefore, in many scientific publications a combination of total fluorine measurements with targeted measurements is described for the evaluation of the overall PFAS content.

To address the disadvantage of the total fluorine methods that also non-PFAS fluorine (i.e. not restricted) is included in the measurement if present in the sample, an obligation to disclose information about the fluorine content of a product is introduced. Under this regime, when the measured total fluorine in a product exceeds 50 mg F/kg during enforcement, the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. This will facilitate the check for compliance with the concentration limit for PFASs, including polymeric PFASs (50 ppm). The information requirement would also facilitate the practicality and enforceability of the proposed restriction using total fluorine analytical methods. This condition would allow the total fluorine limit value to be used in the restriction for overall content of PFASs in addition to the limit for specific PFASs as measured with targeted analysis.

Standard analytical methods for PFASs would be very helpful and facilitate the enforcement of the proposed restriction. Development of such methods is therefore highly encouraged by the Dossier Submitters. However, in the absence of European (or international) standard analytical methods for PFASs in all matrices covered by the proposed restriction, there are different opportunities for checking compliance with the proposed restriction. Methods can be organised as accredited, standard, validated and research methods, where the former has the most stringent classification. It is advised to use an accredited method in an accredited laboratory when this is available. These methods have been (1) extensively developed and tested, (2) have an inherent quality control guarantee, (3) are cross checked regularly between accredited laboratories and regulatory organs and (4) follow a fixed protocol that cannot be deviated from. This leads to results that can be compared between different laboratories, regions, time points, etc. When an accredited method is not available, it is advised to use a standard or at least a validated method. This validation should be as extensive as possible covering accuracy, precision, linearity and application range, limit of detection (LOD), limit of quantification (LOQ), selectivity/specificity, recovery and robustness/ruggedness. Extensive validation leads mostly to results with a sufficient confidence to be used for reporting or as with accredited methods to compare between different laboratories, regions and time points. Considering the availability of analytical methods on the market to measure the content of various PFASs, the ROs are concluded to be practicable and enforceable with regards to analytical methods and concentration limits.

Analytical methods are further described in Annex E.4.

### 2.5.4. **Fluorine mass balance**

There are different advantages and disadvantages with the various analytical methods for PFAS. Some methods are not able to detect all different kinds of PFAS, and in some cases certain PFAS are omitted from or lost during sample preparation (intentionally or unintentionally). In order to get a complete picture of PFAS present in a sample or understand fully what is happening with PFAS during a transformation step, a fluorine mass balance can be included in the assessment. In contrast to that of other organic micropollutants, the degradation of PFAS can be readily monitored by tracing the fluorine element. By choosing the analytical methods wisely in a systematic manner, it can be possible to get a better overview of what is known and what is not known about the presence of PFAS in a sample, i.e. how much of the complete picture are the analyses covering.

For example, Smith et al. (2024) investigated approaches to fluorine mass balance when working with technologies for PFAS destruction. However, the considerations related to analytical methods in the study apply equally well to other types of samples. In Figure 8 below, from their paper, it is indicated which analytical methods cover what types of PFAS. The relative sensitivity, analyte coverage and level of structural detail is indicated by colours, shapes and sizes of boxes in the figure. By combining different analytical methods, it is possible to cover a large part of the different PFAS substances, and in some cases calculations to check that all fluorine has been accounted for can be made.

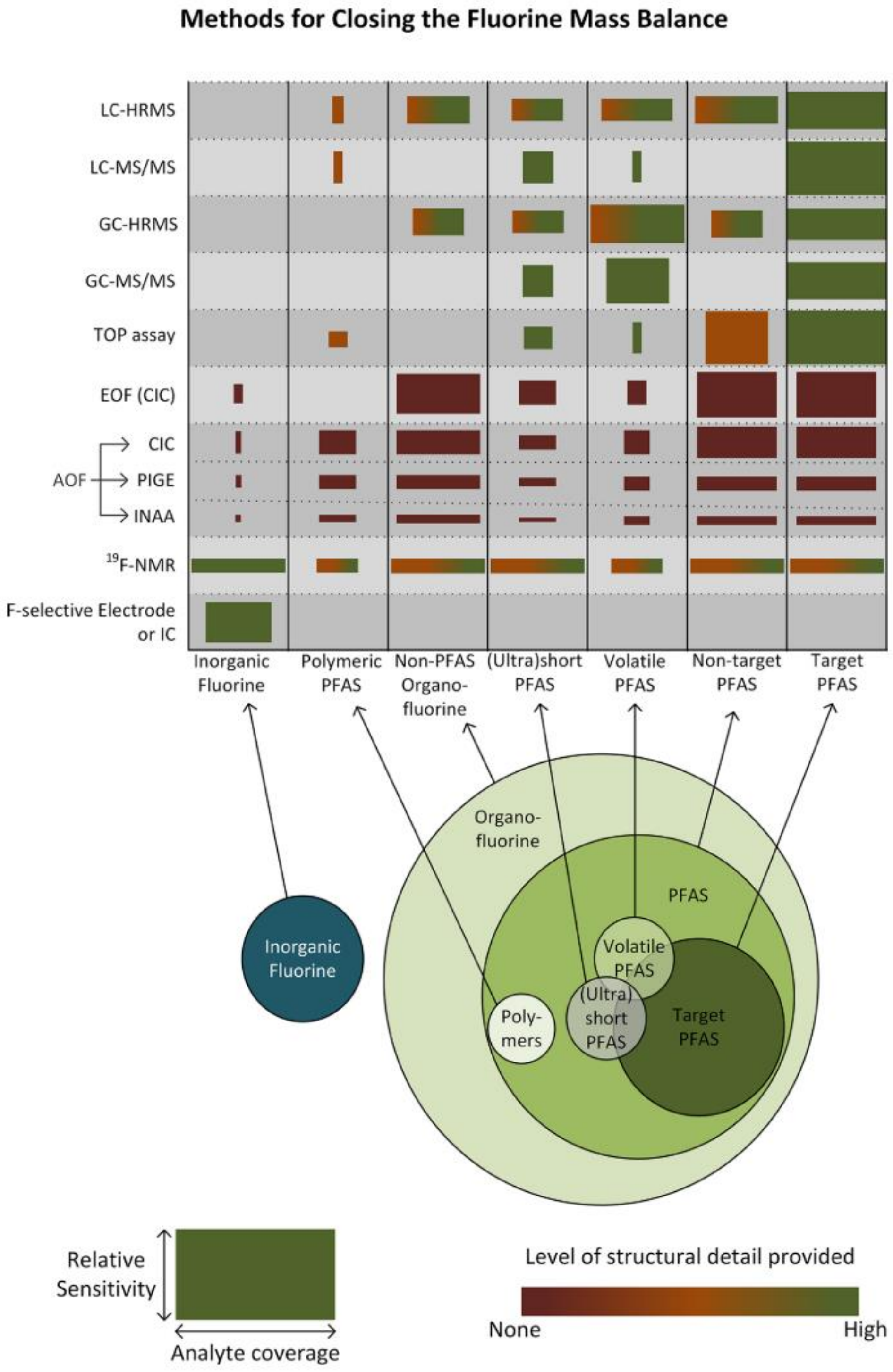

**Figure 8. Analytical methods relevant for a fluorine mass balance (Smith et al., 2024).**

## 2.5.5. **Sampling strategy and approach to enforcement**

A sampling strategy and an approach to enforcement is needed for a restriction. One such approach could be the method explained by Koch et al. (2020). The authors suggest a top-down approach for the comprehensive assessment of organic fluorine, starting with the measurement of total fluorine or extractable organic fluorine (EOF), see Figure 9 below. Based on the results from the initial analyses, samples of interest are selected for further determination of the specific organic fluorine content. These samples are subjected to targeted PFAS analysis. By comparing the sum of targeted PFAS with the total fluorine measurements, the unquantifiable organic fluorine may be obtained by mass balance calculations. For further identification of unquantifiable organic fluorine, approaches such as total oxidizable precursor assay, suspect and non-target screening may be applied. In cases with limited time or resources, or when the identity of the unknown organic fluorine substances is not needed, elements from this plan could be used without doing the full analysis.

The mass balance calculations may follow the scheme outlined in Figure 9.

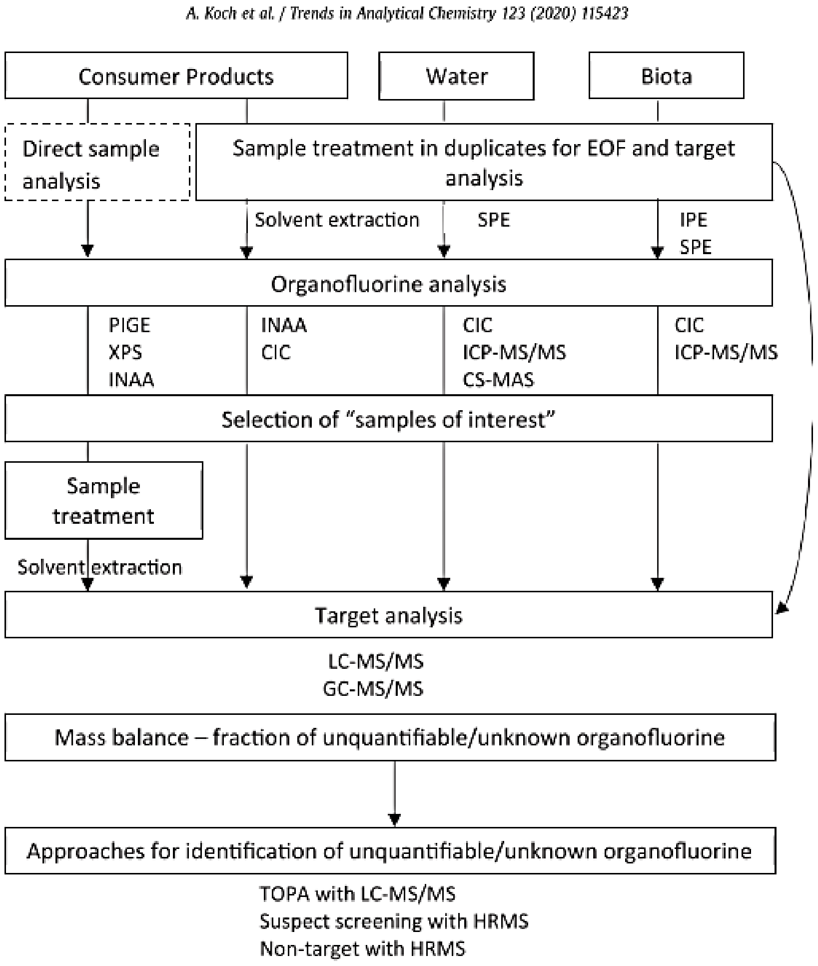
A. Koch et al. / Trends in Analytical Chemistry 123 (2020) 115423

**Figure 9. Proposed workflow for a comprehensive organic fluorine assessment. Source: Koch et al. (2020). SPE = solid phase extraction; IPE = ion pair extraction; PIGE, XPS, INAA, CIC, ICP-MS/MS, CS-MAS = different methods for fluorine measurements, see Annex E.4. or paper.**

Similar to other REACH restrictions, not all products on the market are subject to enforcement controls. Rather, certain products are selected for chemical analysis according to enforcement plans and strategies. Likewise, it is not expected that a product selected for chemical analysis during enforcement, is necessarily analysed according to all three concentration limits. It is up to the authorities to select which parameters of the regulation a product will be controlled against. Sometimes targeted PFAS analysis may be performed, while alternatively, products may be checked for compliance with the total PFAS limit value, etc. This is up to the discretion of enforcement authorities.This restriction proposal covers a broad range of substances, mixtures and articles and selecting a sample for analysis may need careful consideration. The once-a-product-always-a-product principle should be kept in mind, and samples representative for PFAS content should be selected.

A joint approach for enforcement activities with other regulated PFASs, such as PFHxS, PFOS, PFHxA, PFOA and C9-C14 PFCAs at the same time would increase cost effectiveness in the enforcement as compared to inspecting the substances individually. In addition, border authorities can control compliance of imported articles using Safety Gateto report any violation of the restriction.

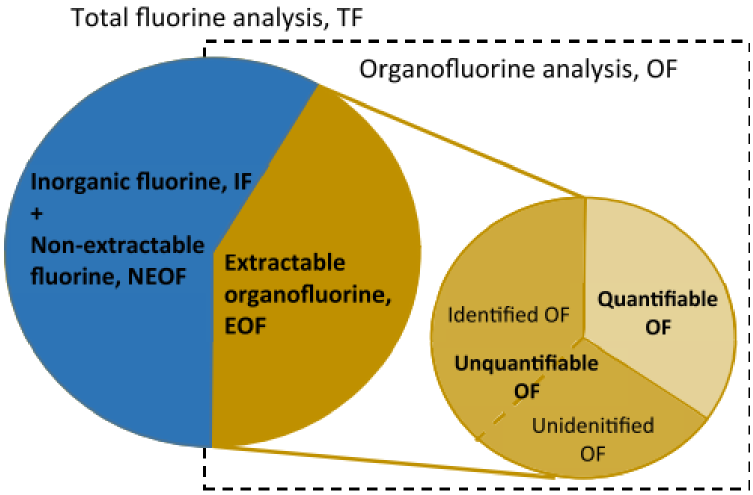

**Figure 10. Mass balance analysis of fluorine. Source: Koch et al. (2020).**

Vestergren et al. (2024) investigated a possible systematic workflow for compliance testing according to coming classwide regulations on PFAS, including the universal PFAS restriction proposal. The study is highly relevant for the PFAS restriction as it considers specifically the opportunities for compliance check of the restriction as proposed in the original dossier. Representatives of the Dossier Submitters are co-authors of the paper to ensure that the regulatory aspects are valid.

According to the paper a three-step workflow is proposed to assess non-compliance with the universal PFAS restriction, see Figure 11.

Step 1 is a screening for total fluorine (TF) which provides a relatively fast and inexpensive way to assess whether PFAS may be present in a sample. A key feature of TF screening (and in contrast to extractable or adsorbable organic fluorine) is that samples are not extracted prior to analysis, making sample preparation relatively easy and allowing all PFAS to be indirectly quantified.

Because TF methods may be subject to false positives from inorganic fluorine or non-PFAS organofluorines, further information may be needed for products that can contain other fluorine sources besides PFAS, Step 2. Information from upstream manufacturers or importers on potential content of inorganic fluorine or non-PFAS organic fluorine could be helpful for this purpose. If reliable information is not available, the presence or absence of $CF_2$ or $CF_3$ groups may be determined analytically. A suitable method does not necessarily need to deduce the exact chemical structure but should be suitable for robustly detecting $CF_2$ or $CF_3$

groups across a wide range of PFAS and products. Examples of methods that may be suitable for this purpose include pyrolysis GC/MS and $^{19}$F NMR, but considerable work is still required to validate these approaches for application in a regulatory context. For example, currently the LOQ for pyrolysis GC/MS tends to be higher than the LOQ for CIC, which means that more development is needed until all of the fluorine content detected with CIC can be confirmed as $CF_2$ or $CF_3$. In addition, it is so far unclear whether the method can separate out substances with $CF_2$ or $CF_3$ units linked to H, Cl, Br or I, which may be out of scope.

In Step 3 specific PFAS are investigated in targeted PFAS analyses with analytical reference standards and compared with the 25 ppb and 250 ppb (sum) limit values. The method is limited by the availability of reference standards. However, in the paper it is recommended to include, at a minimum, measurement of C2−C16 perfluoroalkyl carboxylic acids (PFCAs) and C1− C10 perfluoroalkyl sulfonic acids (PFSAs) after the transformation of their precursors (e.g. TOP assay). The proposed range is based on the prevalence of these PFAA homologues and their precursors in the environment.

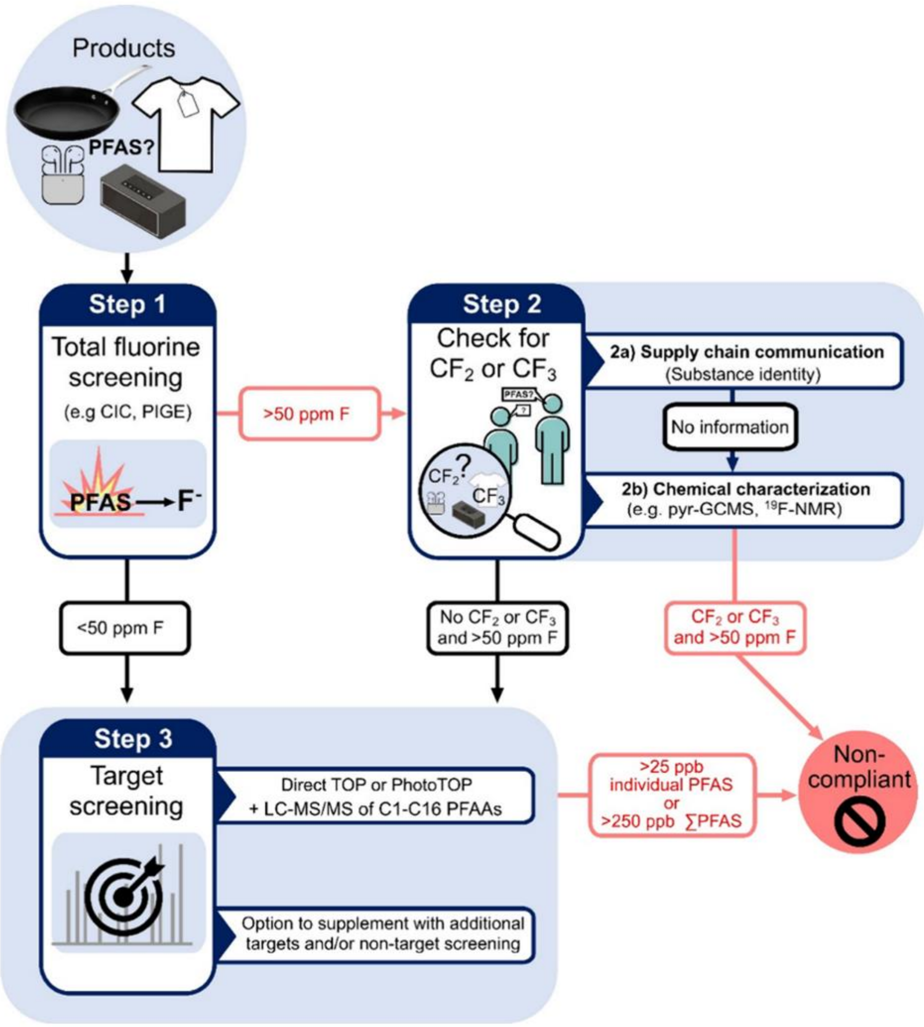

**Figure 11 Proposed workflow for compliance testing (Vestergren et al., 2024).**

### 2.5.6. **Sampling strategy and approach to monitoring**

To monitor the effectiveness of the proposed restriction, time trend monitoring could be performed with relevant samples from the environment or humans. A reduction of PFAS emissions to the environment resulting from this proposed restriction should result in a decreasing PFAS concentration in such a trend monitoring. Relevant environmental and human samples may be analysed according to the strategy developed by Koch et al. (2020) and described above. However, it may take a long time until such decreasing trends are observed in the environment, partly due to the high persistence of PFASs. In addition, degradation of precursors to arrowhead substances represents a long-term source of the PFASs that are usually measured in environmental samples (i.e. arrowheads).

Analytical methods for individual PFASs in various human samples are available and have already been applied in a harmonized way at EU level to evaluate the body burden and how much EU citizens are exposed to PFASs, for example within the HBM4EU network[51]. In addition, a combination of EOF (determined by CIC) and targeted analysis has proven useful and gives an indication of the amount of unidentified PFASs in human samples.

Shen et al. (2024) compiled information on the recent trends in the analysis of PFAS in environmental samples. The study presents advantages and disadvantages with the different approaches to sampling and analysis, and the the authors propose the analytical method workflow for environmental matrices outlined in Figure 12 below. In the figure both standard or traditional methods are indicated, as well as more novel or developing alternatives.

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[51] https://www.hbm4eu.eu/hbm4eu-substances/per-polyfluorinated-compounds/, date of access: 2023-01-06.

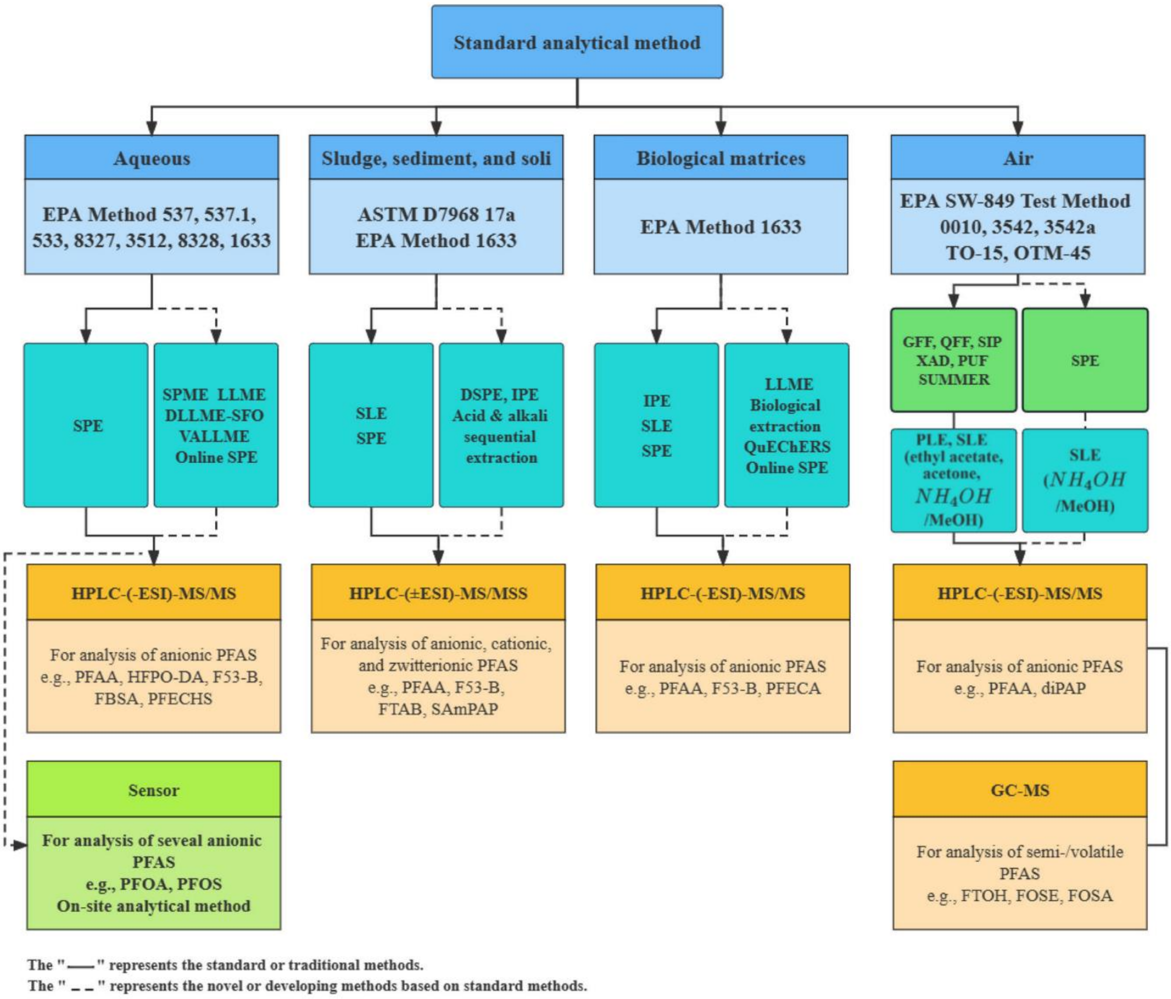

**Figure 12. Analytical method workflow for environmental matrices (Shen et al., 2024).**

In most analytical methods branched and linear PFAS isomers are grouped together and represented as a sum. However, there are a few analytical methods for target analysis of branched isomers only, and research and development in this field is ongoing (Houde et al., 2008). The differentiation between linear and branched isomers of PFAS, as well as the linear vs. branched ratio of substances, have gained attention especially in human and environmental monitoring in the recent years, see e.g. section B.4.2.

An overview of current knowledge of monitoring data and trends for the environmental compartment may be found in Annex B.4.2., while measurement of PFASs in human samples is included in Annex B.9.29. and B.9.30.

An alternative approach to monitoring the effectiveness of the proposed restriction is the monitoring of PFASs in emissions like wastewater and waste streams. If PFASs are phased out of products and uses, a reduction of PFASs in these media could be expected within shorter timelines than reduction in environmental and human samples.

# 3. Uncertainties

The breadth and complexity of the proposed restriction, covering a large number of substances, uses and use sectors and sub-sectors, leads to the presence of a large number of uncertainties in this dossier. These are identified and discussed throughout the dossier and the associated annexes.

Annex F provides an overview of these uncertainties, framed around key questions regarding the presence of risk, the extent of the problem and whether the proposed restriction would be of overall benefit to society. Annex F takes the following approach:

- The structure of the analysis is defined across a series of 28 stages ranging from the identification of sectors using PFASs, the assessment of the quantities of PFASs used and emitted, the environmental and health impact assessment, the analysis of alternatives up to the evaluation of the costs of a restriction.
- The importance of uncertainty at each stage of the analysis is assessed for the final conclusions reached in the dossier.

Returning to the key questions facing the analysis, the following conclusions are drawn on the likely impact of uncertainty:

1. **Is there a risk?**

    a. Persistence of PFASs and degradation products covered by the proposed restriction

The persistence of PFASs is well recognised (Annex B.4.1.). Degradation half-lives of the arrowhead PFASs in the environment exceed the criteria for very persistent substances in Annex XIII of REACH by far.

    b. Potential for health and environmental harm

Ecotoxicity and endocrine activity and effects on human health are documented in Annex B.5. and Annex B.7. for a range of PFASs. Studies show the increasing evidence for effects of low exposures and combined exposures and potential for intergenerational effects (Annex B.4.2.9., B.5.1. and B.7.1.). It is acknowledged that experimental data is limited for many PFASs, in part a consequence of the size of the group of chemicals. However, there is a substantial body of evidence available that demonstrates the risks of PFAS exposure.

***Conclusion on Question 1:***

Despite uncertainties, there is a substantial body of evidence supporting the existence of risks to health and the environment as a result of PFAS use in the EU.

2. **What is the extent of the problem?**

    a. Range of applications of PFASs

The Dossier Submitters have made strong efforts to obtain information from stakeholders through a variety of channels (including public consultations (CfE), technical discussions and scientific literature). Evidence has been gathered (Annex A) to identify a wide range of applications of PFASs both by sector and by specific activities within those sectors. From literature and stakeholder consultations some additional uses/applications were identified. For these however no detailed assessment was performed, because they concerned niche applications or because the applications are currently of little relevance in the EU. For some uses, the Dossier Submitters decided to await further input from the Annex XV consultation in 2023 to fully assess them. Based on this input, the following additional uses were also assessed:

- Printing applications

- Sealing applications
- Machinery applications
- Other medical applications
- Military applications
- Explosives
- Broader industrial uses

Furthermore, for some of the already established uses new information from the consultation on the Annex XV report led to the addition of further sub-uses. It is recognized though that it is impossible to provide a fully exhaustive inventory of uses, tonnage and emission estimates given the large number of PFASs and the broad range of processes and products they are used in. Given the extent of stakeholder engagement, it is envisaged that the vast majority of uses of PFASs have been identified. There is a good understanding of the desired functions and properties provided by PFASs for each application.

b. Quantities of PFASs produced/used

Information on amounts of non-polymeric and polymeric PFASs produced and used in the EU/EEA and additionally imported as chemical mixtures and in articles is limited, with the exception of fluorinated gases for which reporting mechanisms exist linked to the UN Framework Convention on Climate Change and the EU's F-Gas Regulation. Some specific problems are noted, for example PFASs are often not listed as ingredients and tonnages imported and exported in articles are unclear. There is also concern that there may be significant illegal import of fluorinated gases. However, sufficient information is available to provide a broad indication on which activities are linked to the most substantial use of PFASs and which are minor uses (see Table 3 and Table 4). In some cases, double counting of tonnages has to be expected, as some uses have overlaps in their applications. Overlaps occurred for HVACR applications, greases, etc. For e.g. HVACR these were separated between the uses applications of fluorinated gases and transportation and only one use (transportation) took them forward for calculation of emissions. For greases, which are mainly assessed in lubricants, these were also mentioned partly in other uses. Thus, to some small extent double counting took place here. Uncertainty in the quantities of PFASs used increases over time, though there is a sound basis for concluding that without regulation the amounts used would increase across a growing list of applications.

c. Quantities of PFASs emitted

A range of ±21% around the central estimate of 73 092 t/y has been calculated for use phase emissions of total PFASs in 2020. When looking at the different PFAS subgroups these ranges are ±49% for polymeric PFASs, ±62% for PFAAs and PFAA precursors, and ±6% for fluorinated gases (see Table 1). Emissions are expected to continue increasing year on year in line with expanding use of PFASs, though the extent of this growth is uncertain.

d. Fate of emissions

Tracking of emissions across the life cycle for each use has not been attempted. However, knowledge of long-range transport potential, mobility, accumulation in plants and bioaccumulation supported by monitoring data is considered sufficient by the Dossier Submitters to support the proposed restriction. It is acknowledged that currently there are no tools available for reliable prediction of future exposures. However, there is high potential for ubiquitous, increasing and irreversible exposure of the environment and humans based on the general knowledge on degradation pathways and, more specifically, the observations from monitoring data, model data, degradation testing and information on mobility and volatility. There is high potential for human exposure via food and drinking water and other routes including dusts and gases in indoor and outdoor air (Annex B).

***Conclusion on Question 2:***

There are uncertainties in the quantities of PFASs used and emitted in the EU. However, there is good evidence on the overall scale of emissions of PFASs for 2020, these emissions will continue to grow over time due to the expected economic growth. There are uncertainties in use and emissions from individual activities, but information is sufficiently reliable to provide a good understanding of the ranking of activities (see Table 4) and the overall scale of use and emissions. It is concluded that there is a high risk of environmental and human exposure linked to PFAS use in the EU.

## 3. Is the proposed restriction of overall benefit to society?

### a. Proportionality of the restriction in general

The dossier reviews evidence on alternatives and their availability and applicability, and on costs to industry, consumers and society from the restriction. There are, inevitably, uncertainties in all of these parameters to a greater or lesser extent. Direct assessment of proportionality has not been possible given that there is insufficient data to enable detailed modelling of costs to industry, etc. and/or of benefits via reduced impacts to ecosystems and human health. However, the persistent nature of PFASs, against a background of high and growing levels of use and emissions will, in the absence of a restriction, lead to a growing environmental stock of PFASs. This strongly indicates that the longer use and emissions continue, the greater the burden on society.

### b. Proportionality of specific derogations to the restriction

It is recognised that some applications will have greater difficulty in transitioning away from PFASs than others. Reasons for this include a lack of (assessment of) alternatives at the present time, and the presence of technical or regulatory barriers. Derogation periods have been defined for a number of applications based on the information obtained from the literature and feedback from stakeholders. This is designed to mitigate potentially significant problems that may be encountered. There remains uncertainty however, regarding whether enough time, or too much time is provided under the proposed derogations.

### ***Conclusion on Question 3:***

The Dossier Submitters conclude that the proposed restriction would be of overall benefit to society, recognising the consequences of continual use and emissions of PFASs into the future and the availability of viable alternatives for many uses. It is acknowledged that there remain uncertainties in the dossier that may affect the quality of the conclusions reached on specific sectors and applications. The consultation on the Annex XV report provided further substantiated information to reduce these uncertainties (see Annex F).

# 4. Conclusion

All PFASs in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment. As a consequence, if releases are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are increasingly likely. In such an event, the exposures are practically irreversible. The resulting damage to the environment and human health is expected to last for long periods (decades to centuries). Even if further releases of PFASs were immediately prevented, existing technical and environmental stocks would continue to be a source of exposure for generations to come. The societal costs arising from such damage cannot be quantified, but existing evidence suggests that they can be very high. There are several concerns arising from the use of PFASs, e.g. that ubiquitous and unavoidable contamination of drinking water resources is to be expected unless releases are minimised. Human exposures can occur via all exposure routes and cannot be easily avoided or mitigated. Some PFASs can accumulate in (edible parts of) plants, while others have bioaccumulation potential in other biota and humans. PFASs are also transmitted effectively from the exposed mother to unborn and breastfed children. The various uses of PFASs, as described in section 1.3.1, are contributing to long-term general human and environmental exposures to PFASs.

Information to derive a robust predicted no effect concentration (PNEC) as well as a predicted environmental concentration (PEC) is currently insufficient. Therefore, it is not possible to conclude whether risks are adequately controlled, either now or in the future. Even though not all PFASs are PBT substances, the concerns raised for them compare with the concerns for PBT/vPvB substances. Additional concerns regarding mobility and long-range transport potential of PFASs therefore justify a non-threshold approach. The Dossier Submitters conclude that PFASs should be treated as non-threshold substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk. The proposed restriction enables a regulatory path to reduce emissions of PFAS, thereby mitigating the level of general PFAS exposures.

In accordance with previous restriction proposals on non-threshold substances, the Dossier Submitters conclude that every emission to the environment increases the likelihood of adverse effects. Therefore, current and future emissions have to be minimized. Previous restriction proposals, except for the proposal on PFASs in firefighting foams, only targeted individual PFASs (and their precursors). Furthermore, regulatory initiatives have been taken in non-EU countries such as in Australia, New-Zealand, Canada and several states in the US. This global trend of moving away from PFASs also helps the implementation of the proposed EU-wide restriction. Based on the consideration of possible regulatory measures (see section 2.2.2) and socio-economic impacts, a restriction covering the manufacture, use and placing on the market with specific (mostly time-limited) derogations for several uses is proposed.

The concern should be addressed at EU-level to ensure the functioning of the internal market for PFASs as such, PFASs mixtures and PFAS-containing articles. The substances, mixtures and articles are traded across borders, and it would be less effective, and not meaningful or possible to restrict them nationally due to internal market considerations. Furthermore, due to their high mobility (at least of some PFASs) and persistence, PFAS emissions lead to cross-border pollution.

The need for the restriction of PFASs is based on the following considerations:

- Risks of PFASs are of a non-threshold nature, and should therefore be regulated as a non-threshold substance.

- PFASs are very persistent. PFAS exposures are therefore likely to increase to levels where negative effects are increasingly likely. Once that point has been reached, the exposures are hardly reversible. Besides, PFASs have already been emitted to the environment for decades and represent a pollution problem both locally (near specific sources) and in the general environment. Future emissions will add to the already existing pollution stock.

- Many PFASs are mobile in water, and their potential for long-range transport is high. In combination with high persistence, this means that PFAS exposures in the general environment and the general population cannot be avoided.

- Various PFASs have been found in several environmental compartments such as in sediments, air, surface waters and in marine waters. Also, some drinking water resources and drinking water itself are already contaminated with various PFASs – further highlighting that PFAS exposures cannot be avoided by humans and in the environment.

- Humans and environment are exposed to a complex mixture of PFASs, many of which have so far not been subject to regular targeted monitoring. Effects of combined exposure to this mix of PFASs are likely over time.

- Once emitted, PFASs can only hardly, if at all, be removed from the environment. The high mobility of many PFASs, in combination with the persistence lead to difficulties in removing PFASs from the environment. Filtration of PFASs and degradation during standard treatment processes is difficult and very costly, and would only possibly be efficient if highly concentrated.

- The continued use of PFASs in the various applications described above is estimated to result in about 4.7 million tonnes of emissions to the environment in the EU over the next 30 years unless action is taken.

The proposed restriction on the manufacture, placing on the market, and use of PFASs is justified because:

- The extent of PFAS emissions in combination with its very high persistence and additional concerns warrants regulatory action.

- Information supplied by stakeholders helped to conclude on the suitability and availability of alternatives. Where suitable alternatives for applications are readily available, costs of a restriction are concluded to be generally low or moderate. Mostly time-limited derogations of 5 or 12 years (in addition to the standard 18-month transition period) have been proposed in case the unavailability of alternatives is expected to lead to high or very high costs in the case of a full ban. This approach allows for a transition to alternatives in a way that is expected to mitigate the costs of the proposed restriction (in the form presented in the draft entry text).

- The proportionality of the restriction options ([qualitatively] weighing costs and effectiveness) is assessed for all applications/use sectors, leading to conclusions on the most proportionate restriction option for the respective group of applications/use sector. This approach mitigates unwanted socio-economic impacts.

The proposed restriction as presented in the draft entry text is deemed to be enforceable, implementable and manageable. Based on the information provided, it is concluded that the following thresholds are practicable for PFASs on their own, in another substance, as a constituent, in mixtures or in articles placed on the market:

- 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)
- 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification)
- 50 ppm for total PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

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